

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT DIABETES CARE, INC.,

Plaintiff,

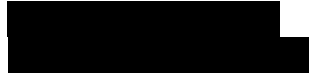
v.

DEXCOM, INC.,

Defendant.

Redacted - Public Version

C.A. No. 21-1699-KAJ



**DEFENDANT'S MEMORANDUM OF LAW IN SUPPORT OF ITS
MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM**

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NATURE AND STAGE OF THE PROCEEDINGS

On December 1, 2021, Plaintiff Abbott Diabetes Care, Inc. (“ADC Inc.” or “Abbott”) filed the Complaint in this action under seal, bringing claims for breach of contract (Count I) and breach of the covenant of good faith and fair dealing (Count II), and seeking a declaratory judgment (Count III) against Defendant DexCom, Inc. (“DexCom”). (D.I. 2; “Complaint” or “Compl.”). Abbott’s Complaint arises from the parties’ 2014 Settlement and License Agreement (D.I. 8-1 Ex. B (“SLA”)), which Abbott claims DexCom breached by suing ADC Inc. and its affiliate Abbott Diabetes Care Sales Corporation (“ADC Sales Corp.”) for patent infringement in the Western District of Texas (“Texas Action”), as well as in Germany and the United Kingdom (the “Foreign Litigation”). Abbott did not serve DexCom with an unredacted version of the Complaint until February 7, 2022. (D.I. 10.)

DexCom moves to dismiss Abbott’s claims pursuant to Federal Rule of Civil Procedure 12(b)(6), and respectfully submits this opening brief in support of its motion.¹

SUMMARY OF THE ARGUMENT

Abbott’s Complaint based on the SLA seeks a second chance at a meritless license defense. Currently, more than a dozen patent infringement or revocation proceedings are pending between DexCom and various affiliates of Abbott, including a matter before this Court, *Abbott Diabetes Care Inc., et al. v. DexCom, Inc.*, C.A. No. 21-977. In the jurisdictions where Abbott may be found liable, Abbott insists that a settlement relating to the parties’ pre-2005 patents prevents DexCom from enforcing intellectual property rights it obtained as late as 2021. Abbott first raised the license argument it presents here in the Texas Action on September 20, 2021, almost three

¹ All internal quotation marks and citations have been omitted, and all emphases supplied, unless noted otherwise.

months after DexCom filed the Complaint in that action.² Needing to justify its argument that DexCom's Texas Action should be adjudicated by this Court, and facing the distinct possibility that the court there will not validate its frivolous license defense, Abbott filed this case. This case—which presents largely the same allegations as Abbott's license defense in the Texas Action—thus comes months after Abbott raised the defense in Texas. Here, Abbott seeks a ruling that the existence of the Texas Action and the Foreign Litigation constitutes a breach of the SLA. But Abbott's Complaint only exists so that Abbott can say it is actively litigating the license issue in the purportedly proper jurisdiction. And even so, it fails to state a claim. Dismissal is warranted.

Two of Abbott's three claims – breach of the implied covenant of good faith and fair dealing (Count II), and declaratory judgment (Count III) – are facially defective. The entirety of Abbott's Complaint relates to the express provisions of the SLA and how DexCom's Texas Action and its Foreign Litigation supposedly breaches them. Abbott has failed to state a claim for breach of an implied covenant because it fails to allege any *implied* term of the SLA, let alone one that DexCom has breached. The declaratory judgment claim is based on and raises the exact same questions as Abbott's breach of contract count, warranting dismissal under controlling law.

Abbott's breach of contract claim is also deficient, as it fails to plausibly allege that DexCom breached its agreement to license certain of its inventions to Abbott. Abbott's pleading requires this Court to construe the definition of the [REDACTED]

[REDACTED] Not only is that interpretation incorrect as a matter of law and directly contrary to Abbott's representations to the court in the Texas Action, it is also wholly unsupported by sufficient factual allegations. Indeed,

² Two weeks later, on October 11, 2021, Abbott made a similar argument in the German component of the Foreign Litigation. (Ex. 1, 10/11/2021 Statement of Defense (citing SLA ¶¶ A.13, H.3).) It still has not made this argument in the UK component of the Foreign Litigation.

Abbott's interpretation would render the license meaningless, because if [REDACTED] [REDACTED] then Abbott would have no license at all, because DexCom can neither patent nor license inventions deemed obvious under section 103. Abbott's entire Complaint asks the Court to "distort or twist contract language" so as to "create new contract rights . . . to which the parties had not assented." *Allied Cap. Corp. v. GC-Sun Holdings, L.P.*, 910 A.2d 1020, 1030 (Del. Ch. 2006). The deficiencies in Abbott's breach of contract claim (count I) are already teed up for the court in the Texas Action, requiring no further opinion from this Court. This Motion therefore does not seek dismissal on that basis.

For these reasons, as explained more fully below, the Court should dismiss Counts II and III of Abbott's Complaint with prejudice.

FACTUAL BACKGROUND

A. The Settlement and License Agreement

On July 2, 2014, DexCom and Abbott resolved three consolidated patent infringement actions (the "Prior Litigation") by executing the SLA, through which each obtained licenses to certain of the other's patent claims. Abbott licensed to DexCom the seven patents it had asserted in the Prior Litigation, plus those claiming priority to those asserted. (SLA ¶¶ A.1, A.2.) DexCom licensed to Abbott certain patent claims on a claim-by-claim basis:

"(a) All worldwide patents and patent applications . . . that DexCom owns [with] . . . an actual filing date before January 1, 2005 [**"Pre-2005 Patents or Applications"**] . . . ;

"(b) All worldwide patents that DexCom owns or has the right to enforce . . . that (i) have issued as of the Effective Date and that, as of May 15, 2014 claimed, or at any time thereafter claim, priority (in whole or in part) to any of [the Pre-2005 Patents or Applications], or (ii) issue in the future from any patent applications currently pending or subsequently filed . . . that . . . claim . . . priority . . . to any [Pre-2005 Patent or Application];

"(c) A claim in a continuation, continuation-in-part, divisional or any other worldwide patent claiming priority to a patent captured in subsection (b), but not claiming priority to [any Pre-2005 Patent or Application] [(in the Complaint, the **"Claiming Criteria"**)], [REDACTED]

[REDACTED]

(SLA ¶ A.13.) [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] are at the heart of the dispute here.

In addition, the parties agreed that the District of Delaware “shall have exclusive jurisdiction over any dispute arising from or under or relating to this Agreement.” (SLA ¶ J.4.)

B. Subsequent Litigation History

Both DexCom and Abbott have obtained numerous patents since executing the SLA. Once the parties’ covenant in the SLA not to sue each other expired, those developments spawned new litigation. On June 30, 2021, DexCom filed the Texas Action, asserting five patents issued to DexCom in 2020 and 2021. (“Patents-in-Suit”).³ (Ex. 2, Tex. Am. Compl. ¶ 2.) On July 1, 2021, DexCom filed patent infringement complaints against Abbott and its affiliates in Germany. The next day, July 2, Abbott sued DexCom in the District of Delaware for patent infringement, asserting twelve patents (*see* Ex. 3 (“First Delaware Action”)); and, two weeks after that, Abbott brought an action in the United Kingdom seeking revocation of the patents that are counterparts to those DexCom is asserting in the German Litigation (*see* Ex. 4, “UK Litigation”). Abbott said

³ U.S. Patent Nos. 11,000,213 (“’213 Patent”), 10,980,452 (“’452 Patent”), 10,702,215 (“’215 Patent”), 10,702,193 (“’193 Patent”), and 10,993,642 (“’642 Patent”). (Compl. ¶ 35.)

nothing about the SLA, let alone about licensing, in either case where it sought redress for alleged infringement.

Then, on September 20, 2021, Abbott sought transfer of the Texas Action to this Court on the basis of the forum selection clause in the SLA, and its new theory that “[e]very patent claim DexCom is asserting here falls within the scope of its license” because “DexCom’s Licensed Patents” include all [REDACTED] of the subject matter of” DexCom’s pre-2005 patents,” and therefore are governed by the SLA’s forum selection clause. (Ex. 5 (“Motion to Transfer”) (quoting SLA ¶ A.13).) Abbott attached lengthy claim charts to its Motion to Transfer purporting to show how each of the Patents-in-Suit is [REDACTED] of an earlier DexCom patent or application, which Abbott presented as prior art establishing obviousness consistent with the standard for obviousness set for in 35 U.S.C. § 103. (MTT. at 7; Exs. 6-10, (Mot. Exs. H, I, M, N, & O).)⁴ Abbott was even more explicit about its interpretation of the SLA’s “obvious variant” term in the German Litigation, when it argued through a proffered expert on U.S. patent law that all of DexCom’s claims in the German Litigation are [REDACTED] [REDACTED] (10/11/2021 Statement of Defense (citing SLA ¶¶ A.13, H.3)), and that the German court must refer to [REDACTED] to interpret the [REDACTED] (Ex. 11, Lewis Decl. ¶ 43.)⁵

Following jurisdictional discovery in the Texas Action, DexCom opposed Abbott’s Motion to Transfer on February 9, 2022, arguing that Abbott’s invocation of the SLA’s forum selection

⁴ 35 U.S.C. § 103 provides: “[a] patent for a claimed invention may not be obtained, . . . if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.

⁵ Even though the German Litigation and the UK revocation action involve the same patents, Abbott has never raised its [REDACTED] in the UK proceeding.

clause, dependent as it was on 35 U.S.C. § 103, was non-sensical and frivolous for several reasons, including that claims that are obvious can neither be patented nor licensed. (Ex. 12, MTT Opp.) In reply, Abbott reversed course, arguing that DexCom's assertion that Abbott had taken the position that the SLA's [REDACTED] provision was to be interpreted in terms of 35 U.S.C. § 103 was "unexplained, untrue, disputed, and for [a] Delaware court to decide." (Ex. 13, MTT Reply at 1.)⁶

C. Allegations in the Complaint

Meanwhile, five months after Abbott first sued DexCom in this District and the United Kingdom without raising the SLA, and two months after asserting its license defense in the Texas Action, Abbott filed this action.

The claims now before this Court parrot the same theory that Abbott initially raised in the Texas Action before it reversed course in response to DexCom's opposition: the Patents-in-Suit are licensed under the provisions of the SLA that grant Abbott a license to [REDACTED] of DexCom's pre-2005 patents and applications, a phrase that refers to the concept of [REDACTED] [REDACTED] (Compl. ¶¶ 16, 37-43.) Abbott does not allege that the SLA actually references that statutory standard; that the phrase [REDACTED] is understood to refer to that standard as a matter or custom or practice; or that the parties had any extracontractual communications, written or otherwise, discussing that standard or establishing their intent to apply it to the license provisions. And when DexCom explained that Abbott's interpretation of "obvious

⁶ This Court "may take judicial notice of the record from a[nother] court proceeding between the parties." *Jonas v. Gold*, 2014 WL 4854484, at *6 (D.N.J. Sept. 30, 2014), *aff'd*, 627 F. App'x 134 (3d Cir. 2015) (citing *Oneida Motor Freight, Inc. v. United Jersey Bank*, 848 F.2d 414, 416 n. 3 (3d Cir.1988)). Judicial notice is especially appropriate where, as here, court records from different proceeding "contradict [a party's] perfunctory allegations" in the matter at issue." *Lopez v. Howard*, 2007 WL 708989, at *1 (3d Cir. Mar. 9, 2007).

variant” relying on a section 103 analysis was nonsensical, Abbott retreated from the position it offers here (and had initially put forth in its Motion to Transfer in the Texas Action), protesting that DexCom’s claim that Abbott was arguing the “obvious variant” term meant § 103 obviousness was “unexplained, untrue, disputed, and for the Delaware court to decide.” (W.D. Tex. Reply at 1.)

Date	Abbott Filing	Abbott Argument
9/20/2021	Abbott Motion to Transfer in Texas Action (Ex. 9)	“Claim 1 [of DexCom’s 213 Patent] is the ‘epitome’ of obvious . . . under § 103.” (<i>Id.</i> at 8.)
10/7/2021	Lewis Declaration in German Litigation	
12/1/2021	Complaint in this Action	“[T]his action thus raises substantial questions of federal patent law, including . . . the obviousness of certain U.S. patent claims applying 35 U.S.C. § 103.” (D.I. 2 ¶ 16.)
2/23/2021	Abbott Reply in Further Support of Motion to Transfer in Texas Action (Ex. 13)	“The SLA just [REDACTED] (Id. at 2.)

Were the applicability of the SLA not already squarely before the court in the Texas Action, DexCom would raise several arguments for dismissing Abbott’s breach of contract claim here.⁷ Abbott cannot state a claim for breach of contract based on their interpretation of the “obvious variant” provisions, which must be read “in a way that gives effect to every term of the instrument,

⁷ Not least of these would be Abbott’s own position in the Texas Action, which undercuts any claim that [REDACTED] (*See also*, Ex. 12, MTT Opp.) However, no matter what Abbott’s real view of the SLA is, it would be plainly unreasonable to adopt the interpretation of a party that vociferously disclaimed it 6 weeks ago, especially where it is facially unsupported and the Complaint contains no allegations to support it. *Allied Cap.*, 910 A.3d at 1030 (refusing to “twist and torture” meaning of obligation).

and that, if possible, reconciles all of the provisions of the instrument when read as a whole,” *Council of Dorset Condo. Apartments v. Gordon*, 801 A.2d 1, 7 (Del. 2002), and which is consistent with “what a reasonable person in the position of the parties would have thought the language of the contract meant,” *Smartmatic Int’l Corp. v. Dominion Voting Sys. Int’l Corp.*, 2013 WL 1821608, at *4 (Del. Ch. May 1, 2013). For starters, Abbott pleads no facts from which this Court could infer that a reasonable person would understand [REDACTED]

[REDACTED] Indeed, the contract language surrounding the term “obvious variant” rebuts Abbott’s reading. Where DexCom and Abbott intended a statutory standard to govern the scope of Abbott’s license, they cited the applicable provision. (*See, e.g.*, SLA ¶ A.13 (licensing to Abbott [REDACTED]

Moreover, as DexCom has explained in the pending MTT briefing in the Texas Action, Abbott’s interpretation of [REDACTED] is inherently unreasonable, unworkable, and, therefore, implausible. DexCom and Abbott could not agree to license claims that are “obvious” under 35 U.S.C. § 103, because such claims cannot be patented: “[a] patent for a claimed invention may not be obtained, . . . if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious.” 35 U.S.C. § 103. And, of course, DexCom could not grant Abbott a license to something it did not own. In other words, Abbott’s breach of contract claim depends on an interpretation of “obvious variant” which confers no enforceable rights to Abbott and imposes no enforceable obligations on DexCom.

LEGAL STANDARDS

To survive a motion to dismiss under Rule 12(b)(6), a complaint must present “sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678, (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)).

However, a court is “not bound to accept as true a legal conclusion couched as a factual allegation.” *Twombly*, 550 U.S. at 555. Rather, plaintiff must “provide the ‘grounds’ of his ‘entitle[ment] to relief’ beyond ‘labels and conclusions.’” *Cornell Univ. v. Illumina, Inc.*, 2012 WL 1885129, at *2 (D. Del. May 23, 2012) (quoting *Twombly*, 550 U.S. at 555)). Allegations are facially plausible if they “allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Iqbal*, 556 U.S. at 678. Determining plausibility is “a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.” *Id.* at 679. “Where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not ‘show[n]’—‘that the pleader is entitled to relief.’” *Id.* (quoting FED. R. CIV. P. 8(a)).

District courts in the Third Circuit have adopted a “three-step process . . . [for] reviewing the sufficiency of a complaint:

“First, the court must ‘tak[e] note of the elements [the] plaintiff must plead to state a claim.’ Second, it ‘should identify allegations that, ‘because they are no more than conclusions, are not entitled to the assumption of truth.’” And third, “[w]hen there are well-pleaded factual allegations, [the] court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief.”

Robinson v. Fam. Dollar Inc., 679 F. App’x 126, 131–32 (3d Cir. 2017) (quoting *Connelly v. Lane Constr. Corp.*, 809 F.3d 780, 787 (3d Cir. 2016)).

In the Third Circuit, a declaratory judgment may only issue where it would “be of significant practical help in ending the controversy.” *Benson v. Amguard Ins. Co.*, 2017 WL 2672078, at *3 (D. Del. June 21, 2017) (quoting *Step-Saver Data Sys., Inc. v. Wyse Tech.*, 912 F.2d 643, 650 (3d Cir. 1990)). A claim that “relies on the same facts and allegations as the prior counts” offers no such help. *OC Tint Shop, Inc. v. CPFilms, Inc.*, 2018 WL 4658211, at *9 (D. Del. Sept. 27, 2018) (dismissing a declaratory judgment claim raising same issue as breach of

contract claims). When “the declaratory judgment claim bears ‘complete identity of factual and legal issues’” with another count in the complaint, the claim “adds nothing to an existing lawsuit, [and] need not be permitted.” *JJCK, LLC v. Project Lifesaver Int’l*, 2011 WL 2610371, at *6 (D. Del. July 1, 2011) (quoting *Aldens, Inc. v. Packel*, 524 F.2d 38, 51 (3d Cir. 1975)).

“To sufficiently allege a claim for breach of the implied covenant of good faith and fair dealing, a plaintiff must allege (1) *a specific obligation implied in the contract*, (2) a breach of that obligation, and (3) resulting damages.” *OC Tint Shop*, 2018 WL 4658211, at *4. An implied term “cannot override the express contract language.” *Kyle v. Apollomax, LLC*, 987 F. Supp. 2d 519, 528 (D. Del. 2013). Rather, an implied term can only be actionable if the contract is “truly silent with respect to the matter at hand.” *Allied Cap.*, 910 A.2d at 1032.

ARGUMENT

I. ABBOTT’S CLAIM FOR DECLARATORY JUDGMENT SHOULD BE DISMISSED AS DUPLICATIVE AND LACKING A USEFUL PURPOSE.

Abbott’s claim for declaratory judgment (Count III) is entirely duplicative of its breach of contract claim (Count I) and would thus serve “no useful purpose” because “the controversy would be resolved by the disposition of another claim in the case,” i.e., Abbott’s breach of contract claim. *See Christiana Care Health Servs., Inc. v. PMSLIC Ins. Co.*, 2015 WL 6675537, at *5 (D. Del. Nov. 2, 2015). Abbott seeks a judgment establishing that the patents asserted by DexCom in the Texas Action and the German Litigation are either licensed or precluded from infringement under the SLA. (Compl. ¶ 93.) Its right to that requested relief depends entirely on this Court’s interpretation of the SLA, which is the same issue raised in the breach of contract claim. A claim for a declaratory judgment so obviously “duplicative” and “redundant” should be dismissed. *JJCK, LLC v. Project Lifesaver*, 2011 WL 2610371 at *6. Abbott fails to state a claim for declaratory judgment, and Count III should be dismissed.

II. ABBOTT FAILS TO STATE A CLAIM FOR BREACH OF THE COVENANT OF GOOD FAITH AND FAIR DEALING.

The Court should dismiss Abbott’s claim for breach of the implied covenant of good faith and fair dealing (Count II) because it fails to allege any implied contract term for this Court to read into the SLA.

Abbott’s claim for breach of the implied covenant of good faith and fair dealing relies on the same provisions of the SLA, and covers the same subject matter, as its breach of contract claim. It does not depend on any additional implied terms. In fact, its allegations for this Second Cause of Action refer back to the “breaches alleged in Paragraph 80” of the breach of contract claim, confirming that both counts relate to the same conduct and the same alleged violations of the SLA. (Compl. ¶ 86.)

Count I (Breach of Contract)	Count II (Breach of Implied Covenant)
<p>“DexCom materially breached the SLA in at least five, separate and independent ways: [REDACTED] (2) by initiating and maintaining U.S. and foreign patent litigations . . . , (3) by maintaining those litigations outside of the agreed-upon forum “exclusively” permitted by the SLA, (4) by failing to engage in the SLA’s required dispute resolution process before initiating its . . . litigations . . . , and (5) by failing to engage in the SLA’s required dispute resolution process after ADC Inc. initiated that process” (Compl. ¶ 80.)</p>	<p>“To the extent DexCom argues or the Court finds that any of the breaches alleged in Paragraph 80 above are not breaches of the SLA’s express terms, they are at minimum breaches of the SLA’s implied covenant of good faith and fair dealing. . . . DexCom has materially breached the implied covenant of good faith and fair dealing by filing and maintaining its W.D. Tex. Litigation and the Foreign Litigations.” (<i>Id.</i> ¶¶ 86-87.)</p>

This is exactly what Delaware law does not allow. *See, e.g., OC Tint Shop*, 2018 WL 4658211 at *5 (dismissing a good faith and fair dealing claim because “the contract specifically addresses the conduct that Plaintiff has alleged as Defendant’s breach of the duty of good faith and fair dealing”); *Kuroda v. SPJS Holdings, L.L.C.*, 971 A.2d 872, 888 (Del. Ch. 2009) (“To the extent that Kuroda’s implied covenant claim is premised on the failure of defendants to [perform]

under the contract, the claim must fail because the express terms of the contract will control such a claim.”). Abbott cannot sufficiently plead a breach of the implied covenant of good faith and fair dealing simply by regurgitating its allegations regarding breaches of the SLA. *Caldera Props.-Lewes/Rehoboth v. Ridings Dev., LLC*, 2008 WL 3323926, at *16 (Del. Super. Jun. 19, 2008) (pleading party “cannot take the basis of a breach of contract claim and say it constitutes a breach of the implied covenant”). Yet that is exactly what Abbott has done here.

Nor can Abbott plead such a claim in the alternative. Abbott asks this Court to allow its implied covenant claim to proceed “[t]o the extent DexCom argues or the Court finds that any of the breaches alleged in Paragraph 80 above are not breaches of the SLA’s express terms.” (Compl. ¶ 86.) Again, these allegations fail to identify any implied obligation or “an ambiguity or potential gap in a contract that could be filled by the implied covenant.” *Fortis Advisors LLC v. Dialog Semiconductor PLC*, 2015 WL 401371, at *5 (Del. Ch. Jan. 30, 2015). As the court held in *Fortis Advisors* when dismissing implied covenant claims pleaded alternatively, the “right to plead alternative claims . . . does not obviate the need to provide factual support for each theory.” *Id.*; see also *Roma Landmark Theaters, LLC v. Cohen Exhibition Co. LLC*, 2020 WL 5816759, at *10 (Del. Ch. Sept. 30, 2020) (adopting *Fortis Advisors* rationale). The Complaint contains no allegations that would suffice to plead this count in the alternative.

The doctrine of good faith and fair dealing has a “narrow purpose” and is “rarely invoked successfully.” *Narrowstep, Inc. v. Onstream Media Corp.*, 2010 WL 5422405, at *10 (Del. Ch. Dec. 22, 2010). Abbott has not cleared that high bar, and Count II should be dismissed.

CONCLUSION

For all the reasons above, DexCom respectfully requests that the Court dismiss Counts II and III of ADC Inc.'s Complaint.

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CERTIFICATE OF SERVICE

I, Nathan R. Hoeschen, hereby certify that on April 11, 2022, this document was served on adc-mnat@list.mnat.com and the persons listed below in the manner indicated:

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EXHIBIT 1

Redacted in its entirety

EXHIBIT 2

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
WACO DIVISION**

DEXCOM, INC.,

Plaintiff

v.

ABBOTT DIABETES CARE, INC.,
ABBOTT DIABETES CARE SALES CORP.

Defendant.

Civil Action No.: 6:21-cv-690

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff DexCom, Inc. (“DexCom” or “Plaintiff”), through its undersigned counsel, brings this action against Abbott Diabetes Care, Inc. and Abbott Diabetes Care Sales Corp. (collectively, “Abbott” or “Defendants”). In support of this Complaint, DexCom alleges as follows:

THE PARTIES

1. Plaintiff DexCom, Inc. is a Delaware corporation having its principal place of business at 6340 Sequence Drive, San Diego, CA 92121.
2. DexCom is the owner by assignment of U.S. Patent No. 11,000,213 (“the ’213 Patent”) (attached as Exhibit 1), U.S. Patent No. 10,980,452 (“the ’452 Patent”) (attached as Exhibit 2), U.S. Patent No. 10,702,215 (“the ’215 Patent”) (attached as Exhibit 3), U.S. Patent No. 10,702,193 (“the ’193 Patent”) (attached as Exhibit 4), and U.S. Patent No. 10,993,642 (“the ’642 Patent”) (attached as Exhibit 5) (collectively, the “Patents-in-Suit”).
3. Defendant Abbott Diabetes Care, Inc. is a Delaware corporation with its principal place of business at 1360 South Loop Road, Alameda, CA 94502.
4. Defendant Abbott Diabetes Care Sales Corp. is a Delaware corporation with its principal place of business at 1360 South Loop Road, Alameda, CA 94502.
5. Abbott Diabetes Care Sales Corp. is registered to do business in Texas.

6. Abbott Diabetes Care, Inc. and Abbott Diabetes Care Sales Corp. have regular and established places of business in this District, including at 8701 Bee Caves Rd., Austin, TX 78746 and 12501B Research Boulevard, Austin, TX 78759. On information and belief, Abbott Diabetes Care, Inc. employs quality managers, program managers, and manufacturing process engineers among others at those locations. Upon information and belief, Abbott Diabetes Care, Inc. uses and manufactures infringing Abbott products in this district, while Abbott Diabetes Care Sales Corp. uses, offers to sell, and sells infringing products in this district.

7. The Diabetes Care division of Abbott Laboratories, which on information and belief includes at least Abbott Diabetes Care, Inc. and Abbott Diabetes Care Sales Corp., is or has also solicited employees in this district including posting open positions in Austin, Texas for a Project Manager and a Senior Manufacturing Process Engineer.

8. Adam Heller, a co-founder of TheraSense, which was acquired by Abbott in 2004 and became Abbott Diabetes Care, is a professor emeritus in Chemical Engineering at The University of Texas at Austin. <https://che.utexas.edu/faculty-staff/faculty-directory/heller/>

9. Abbott employees in this District will likely have information relevant to the accused products, infringement, and damages, including how the components of the infringing products are sourced, what materials are used in the infringing products, how the infringing products are manufactured, how the infringing products are sterilized, how the infringing products are calibrated, and how many products are manufactured, among other relevant issues.

10. Abbott has placed or contributed to placing infringing products like the Abbott Freestyle Libre 2 Flash Glucose Monitoring System (“Abbott Libre 2”) and the Abbott Freestyle Libre 14 day (“Abbott Freestyle”) into the stream of commerce via an established distribution channel knowing or understanding that such products would be sold and used in the United States, including in the Western District of Texas. On information and belief, Abbott has also derived substantial revenues from infringing acts in the Western District of Texas, including from the sale and use of infringing products like the Abbott Libre 2.

JURISDICTION AND VENUE

11. This is a complaint including causes of action for patent infringement arising under 35 U.S.C. § 271 et seq. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), and 1367.

12. This Court has specific personal jurisdiction over Defendants at least because Defendants conduct business in this Judicial District. DexCom's causes of action arise, at least in part, from Defendants' contacts with and activities in the State of Texas and this Judicial District. Upon information and belief, Defendants have committed acts of infringement within the State of Texas and this Judicial District by, *inter alia*, directly and/or indirectly using, selling, offering to sell, or importing products that infringe one or more claims of the '213 Patent, the '452 Patent, the '215 Patent, '193 Patent, and/or the '642 Patent.

13. Abbott has committed acts within this District giving rise to this action and has established sufficient minimum contacts with the State of Texas such that the exercise of jurisdiction would not offend traditional notions of fair play and substantial justice.

14. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b), (c), and 1400(b) because (1) Defendants have a regular and established place of business in this Judicial District, and (2) Defendants have committed and continue to commit acts of patent infringement in this Judicial District by, *inter alia*, directly and/or indirectly using, selling, offering to sell, or importing products that infringe one or more claims of the '213 Patent, the '452 Patent, the '215 Patent, the '193 Patent, and/or the '642 Patent.

THE PATENTS-IN-SUIT

15. This action involves the following patents: U.S. Patent No. 11,000,213, U.S. Patent No. 10,980,452, U.S. Patent No. 10,702,215, U.S. Patent No. 10,702,193, and U.S. Patent No. 10,993,642.

16. DexCom is the owner, by assignment, of U.S. Patent No. 11,000,213, titled "System and methods for processing analyte sensor data for sensor calibration." A true and correct copy of

U.S. Patent No. 11,000,213 granted by the U.S. Patent & Trademark Office is attached as Exhibit 1.

17. DexCom is the owner, by assignment, of U.S. Patent No. 10,980,452, titled “Analyte sensor.” A true and correct copy of U.S. Patent No. 10,980,452 granted by the U.S. Patent & Trademark Office is attached as Exhibit 2.

18. DexCom is the owner, by assignment, of U.S. Patent No. 10,702,215, titled “Systems and methods for dynamically and intelligently monitoring a host's glycemic condition after an alert is triggered.” A true and correct copy of U.S. Patent No. 10,702,215 granted by the U.S. Patent & Trademark Office is attached as Exhibit 3.

19. DexCom is the owner, by assignment, of U.S. Patent No. 10,702,193, titled “Analyte sensing biointerface.” A true and correct copy of U.S. Patent No. 10,702,193 granted by the U.S. Patent & Trademark Office is attached as Exhibit 4.

20. DexCom is the owner, by assignment, of U.S. Patent No. 10,993,642, titled “Analyte sensor.” A true and correct copy of U.S. Patent No. 10,993,642 granted by the U.S. Patent & Trademark Office is attached as Exhibit 5.

BACKGROUND

21. The human pancreas plays an essential role in converting the food we eat into fuel for the body's cells. The pancreas has two main functions: an exocrine function that helps in digestion and an endocrine function that regulates blood sugar. Two of the main pancreatic hormones are insulin, which acts to lower blood sugar, and glucagon, which acts to raise blood sugar. Maintaining proper blood sugar levels is crucial to the functioning of key, life-sustaining organs including the brain, liver, and kidneys.

22. Diabetes mellitus is a disorder in which the pancreas either cannot create sufficient insulin, or in which insulin is not effective. *See, e.g.*, '213 Patent at 1:40-43. Diabetes comes in two types. A person whose pancreas cannot create sufficient insulin has Type 1 or insulin dependent diabetes. *Id.* A person whose body does not use insulin effectively has Type 2 or non-insulin dependent diabetes. *Id.*

23. More than 34 million Americans suffer from diabetes. <https://www.diabetes.org/resources/statistics/statistics-about-diabetes>. It is the seventh leading cause of death in the United States. *Id.*

24. In the diabetic state, the victim suffers from high blood sugar. *See, e.g.*, '213 Patent at 1:43-47. Left untreated, long-term high blood sugar, or hyperglycemia, can lead to kidney failure, nerve damage, and blindness, among other health related issues. <https://www.mayoclinic.org/diseases-conditions/hyperglycemia/symptoms-causes/syc-20373631>. Treating persistent hyperglycemia often requires insulin. <https://www.mayoclinic.org/diseases-conditions/diabetes/in-depth/diabetes-treatment/art-20044084>. The use of insulin, however, can also be dangerous if not properly monitored. It can lead to the opposite problem, low blood sugar.

25. The condition of having low blood sugar, known as hypoglycemia, in people with diabetes is generally the result of either an inadvertent overdose of insulin, or after a normal dose of insulin, an extraordinary amount of exercise or insufficient food intake. '213 Patent at 1:47-51. Hypoglycemia can be dangerous and if left untreated, it can result in muscle weakness, confusion, unconsciousness, or even death. <https://www.mayoclinic.org/diseases-conditions/diabetic-hypoglycemia/symptoms-causes/syc-20371525>.

26. Historically, people with diabetes often had to carry around and frequently use a self-monitoring blood glucose (SMBG) monitor. SMBGs typically required the patient to prick their finger to collect a small amount of blood that would be used to measure blood glucose levels at that moment in time. '213 Patent at 1:52-54. Because the time intervals between these measurements could be spread far apart, people with diabetes often did not find out they were experiencing hyper- or hypo-glycaemia until it was too late. *Id.* at 1:54-60.

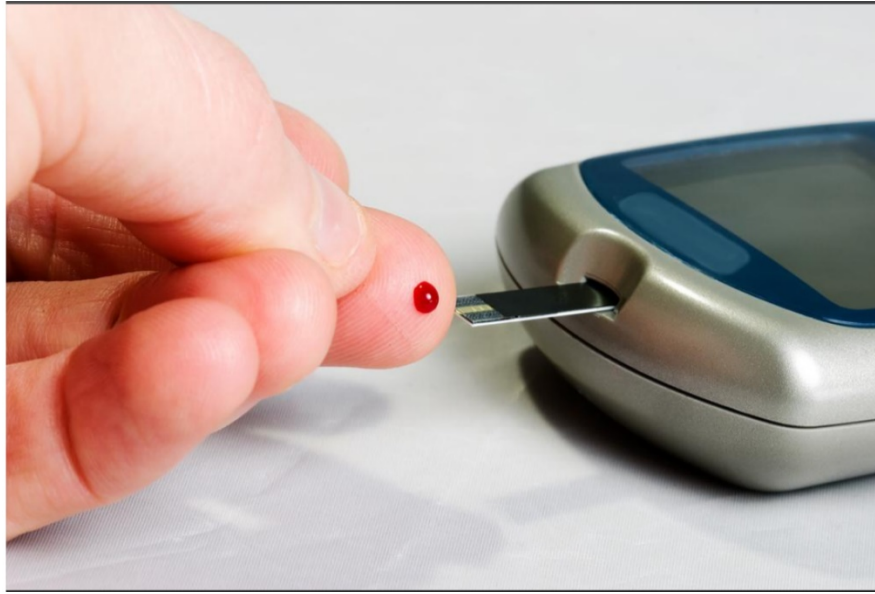


Figure 1

27. DexCom's continuous glucose monitoring systems ("CGMs") offer a more convenient method for tracking glucose levels which can provide more robust data regarding glucose trends as compared to point-in-time SMBG measurements. DexCom's CGMs measure glucose levels in the interstitial fluid. Generally, the monitor itself consists of a sensor that is worn on the body and automatically obtains glucose readings. The data is transmitted to a nearby receiver to display the readings. DexCom's CGMs allow users to see almost immediately when their blood glucose departs from an ideal range, and also allow users (and potentially their care givers and health care providers) to see the trend of their blood glucose. DexCom's CGMs also help people make informed decisions about nutrition, physical activity, and medication.

28. DexCom is a pioneer in the field of CGMs. In 2006, DexCom introduced its first generation CGM to help people more conveniently and effectively manage their blood sugar levels. The Dexcom G5 Mobile was the world's first real time CGM approved for adults and children two years and older. The G5 was also the world's first CGM that could interoperate with an app on a user's smartphone rather than requiring the user to carry around a separate receiver.

29. Today, DexCom sells the Dexcom G6 integrated continuous glucose monitoring ("iCGM") system for determining glucose levels in children two years and older and adults with



INVENTIVE CONCEPTS OF THE PATENTS-IN-SUIT

31. As another example, the ability of certain glucose monitors to be worn for long periods of time raises other types of problems. In order to effectively function for the life of the sensor, the sensor has to be protected from water that would otherwise damage the sensor electronics. The '452 Patent discloses an innovative sealing design that enables the sensor to resist water such as in a shower or a pool and operate continuously over its lifetime.

32. The '215 Patent discloses another innovation DexCom made to improve the usability and benefits provided by the use of glucose monitors. Whereas, prior art glucose monitors required users to check their blood glucose levels to determine whether they were too low or too high, the '215 Patent discloses a system that provides automatic notifications when detected blood glucose levels are at potentially dangerous levels. The two-indicator system disclosed by the '215 Patent further allows the user to be notified before the onset of a hypo-glycemic state so that corrective action can be taken.

33. The '193 Patent discloses a novel arrangement of layers for the transcutaneous sensor that, among other benefits, improves the accuracy of the sensor after insertion as well as the spacing of the electrodes to reduce a user's pain during and after sensor insertion.

34. Each of these patent-protected innovations is used by Abbott without DexCom’s permission in its infringing FreeStyle Libre devices, including but not limited to the FreeStyle Libre 14 day, the FreeStyle Libre 2, and the FreeStyle Libre 3 (collectively, the “FreeStyle Libre Products”).

COUNT I

Abbott's Infringement of U.S. Patent No. 11,000,213

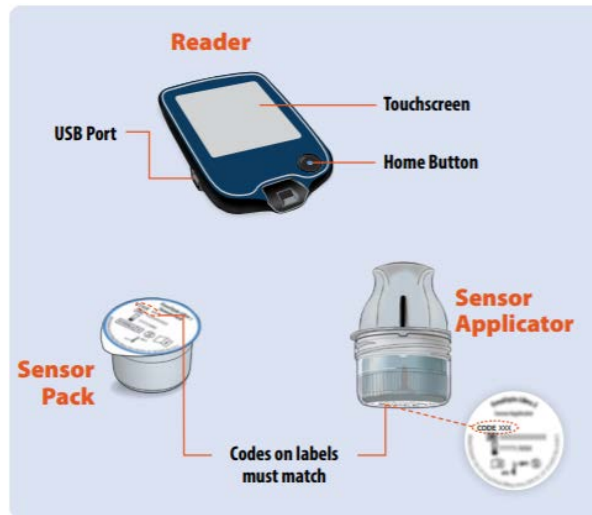
35. DexCom restates and incorporates by reference all of the allegations made in the preceding paragraphs as though fully set forth herein.

36. DexCom is the owner, by assignment, of U.S. Patent No. 11,000,213, titled “System and methods for processing analyte sensor data for sensor calibration.” A true and correct copy of the '213 Patent is attached as Exhibit 5.

37. Abbott has infringed, and is continuing to infringe, literally or under the doctrine of equivalents, at least independent claim 1 of the '213 Patent by making, using, selling, and/or offering for sale its Abbott FreeStyle Libre Products with factory calibration in the United States, in violation of 35 U.S.C. § 271(a). *See, e.g.,* <https://abbott.mediaroom.com/2017-09-27-No-More-Routine-Finger-Sticks-1-for-Americans-with-Diabetes-Abbott-s-FreeStyle-R-Libre-Approved-in-the-U-S>.

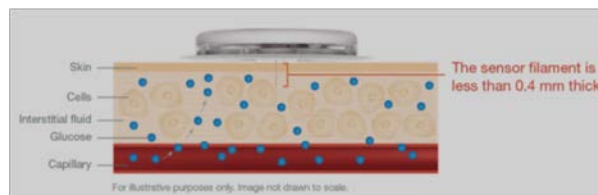
38. At least as of the filing of the complaint, Abbott has knowledge of the '213 Patent.

39. As a non-limiting example, the Abbott Libre 2 is a glucose monitoring system that infringes claim 1 of the '213 Patent.



See, e.g., Abbott Libre 2 User's Manual at 18.

40. The Abbott Libre 2 includes a transcutaneous electrochemical glucose sensor having an in vivo portion configured to be inserted into a body of a host; and an ex vivo portion configured to remain outside of the body of the host.



See, e.g., <https://www.freestyle.abbott/za/en/benefits-of-cgm.html>.

The Sensor measures and stores glucose readings when worn on your body. It initially comes in two parts: one part is in the Sensor Pack and the other part is in the Sensor Applicator. By following the instructions, you prepare and apply the Sensor on the back of your upper arm. The Sensor has a small, flexible tip that is inserted just under the skin. The Sensor can be worn for up to 14 days.

**Sensor**

Measures your glucose while on your body (only visible after applied).

Libre 2 User Manual at 18.

The FreeStyle Libre 2 Flash Glucose Monitoring System uses an electrochemical sensor to monitor glucose levels in the interstitial fluid (ISF). The sensor incorporates both the subcutaneously implanted sensor and associated electronics. The sensor uses a glucose oxidase enzyme to oxidize glucose and transfer electrons to a metal electrode, producing a current. The strength of the current is proportional to the amount of glucose present in the interstitial fluid. The FreeStyle Libre 2 System converts the electrical current signal to a glucose value (in mg/dL) for display on the handheld Reader.

See FreeStyle Libre 2 Flash Glucose Monitoring System FDA 510(k) Substantial Equivalence Determination Decision Summary at Pg. 4.

41. The Abbott Libre 2 includes a processor programmed to calibrate sensor data based at least in part on prior calibration information generated before insertion of the transcutaneous electrochemical glucose sensor in the host, wherein the sensor data is associated with a glucose concentration of the host, wherein the prior calibration information comprises prior sensitivity information associated with the transcutaneous electrochemical glucose sensor, and wherein the processor is programmed to calibrate the sensor data without a need for a reference analyte concentration measurement obtained after insertion of the in vivo portion of the transcutaneous electrochemical glucose sensor.



Images of the Freestyle Libre 2 processor(s) in the sensor and handheld receiver.

What is Factory Calibration?

Factory calibration of sensors removes the need for determining the sensor sensitivity from the user's responsibility and instead places it in the hands of the sensor manufacturer. The sensor sensitivity is determined during the sensor manufacturing process, and that information is included with every sensor in the form of a sensor code. That code can be preprogrammed into the sensor electronics such that no user interaction is required to enter the code, eliminating the risk of transcription error.

The factory calibration process includes the following steps:

- Manufacture sensor lots with low sensor to sensor variability.
- Sample a number of sensors from each sensor lot and test them in the laboratory (in vitro) for their response to glucose and determine their glucose sensitivity.
- Convert the lot glucose sensitivity into a sensor code.
- Program the sensor code into the sensor electronics memory.
- Demonstrate that the initially determined sensor sensitivity does not change over the sensor shelf life.

Since the variation between the sensors in one sensor lot is small, the laboratory tested sensors are representative of the remaining sensors in the sensor lot, which will be used by patients. The code information provides the necessary sensor sensitivity or calibration factor for every sensor in the sensor lot to convert the electrical sensor current into a glucose value. The determination of the code may include corrections for the difference between in vitro and in vivo sensor testing, which can be determined analytically or empirically through clinical trials, and which can be applied universally to all sensor lots.

This process determines how the sensor responds to glucose and will provide glucose data after sensor insertion without the necessity of a BG test by the user. It does, how-

See, e.g., Factory-Calibrated Continuous Glucose Sensors: The Science Behind the Technology, Udo Hoss at S-45 (annotated); *see also* FreeStyle Libre 2 Flash Glucose Monitoring System FDA 510(k) Substantial Equivalence Determination Decision Summary.

42. On information and belief, Abbott, with knowledge of the '213 Patent, and without authority, has actively induced and continues to actively induce infringement by end-users of at least one claim of the '213 Patent, under 35 U.S.C. § 271(b), by intentionally inducing the use, importation, offer for sale, and/or sale of Abbott Libre 2 systems, intending to encourage, and in fact encouraging, end-users to directly infringe the '213 Patent. On information and belief, Abbott actively induced infringement by, *inter alia*, designing and introducing into the stream of commerce the Abbott Libre 2 systems and other infringing CGMs, and by publishing manuals and promotional literature describing and instructing in the operation of the accused devices in an infringing manner and by offering support and technical assistance to its customers that encourage use of the accused products in ways that infringe the asserted claims. In addition, Abbott has had actual knowledge of end users' direct infringement and that Abbott's acts induced such infringement since at least the date of this filing, and when DexCom provided to Abbott a copy of this Complaint.

43. Abbott's infringement has damaged and continues to damage DexCom in an amount yet to be determined, and DexCom will suffer irreparable injury unless the infringement is enjoined by this Court.

COUNT II

Abbott's Infringement of U.S. Patent No. 10,980,452

44. DexCom restates and incorporates by reference all of the allegations made in the preceding paragraphs as though fully set forth herein.

45. DexCom is the owner, by assignment, of U.S. Patent No. 10,980,452, titled "Analyte sensor." A true and correct copy of the '452 Patent is attached as Exhibit 2.

46. Abbott has infringed, and is continuing to infringe, literally or under the doctrine of equivalents, at least independent claim 1 of the '452 Patent by making, using, selling, and/or offering for sale its Abbott FreeStyle Libre Products in the United States, in violation of 35 U.S.C. § 271(a). *See, e.g.*, <https://www.diabetescare.abbott/products.html>.

47. At least as of the filing of the complaint, Abbott has knowledge of the '452 Patent.

48. As a non-limiting example, the Abbott Libre 2 comprises a system for measuring an analyte concentration in a host.



See, e.g., Abbott Libre 2 User's Manual at 18.

49. The Abbott Libre 2 comprises a transcutaneous analyte sensor.

The FreeStyle Libre 2 Flash Glucose Monitoring System uses an electrochemical sensor to monitor glucose levels in the interstitial fluid (ISF). The sensor incorporates both the subcutaneously implanted sensor and associated electronics. The sensor uses a glucose oxidase enzyme to oxidize glucose and transfer electrons to a metal electrode, producing a current. The strength of the current is proportional to the amount of glucose present in the interstitial fluid. The FreeStyle Libre 2 System converts the electrical current signal to a glucose value (in mg/dL) for display on the handheld Reader.

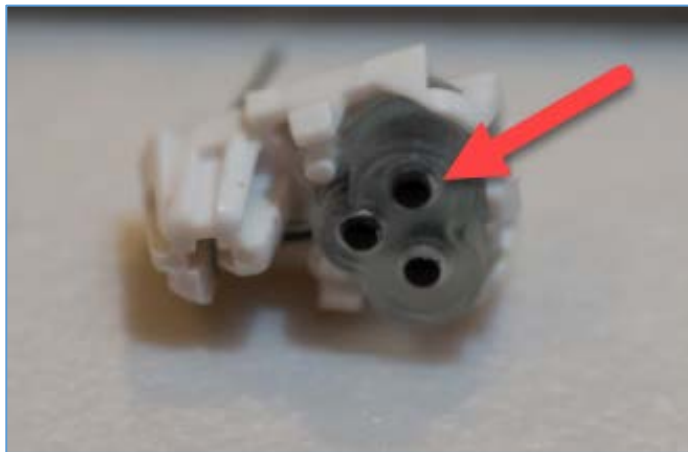
See, e.g., FreeStyle Libre 2 Flash Glucose Monitoring System FDA 510(k) Substantial Equivalence Determination Decision Summary at Pg. 4.

50. The Abbott Libre 2 comprises sensor electronics configured to operatively connect to the transcutaneous analyte sensor.

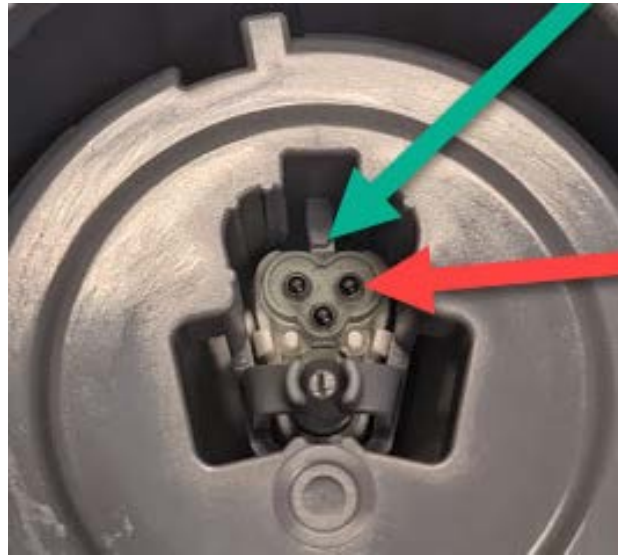
The FreeStyle Libre 2 Flash Glucose Monitoring System uses an electrochemical sensor to monitor glucose levels in the interstitial fluid (ISF). The sensor incorporates both the subcutaneously implanted sensor and associated electronics. The sensor uses a glucose oxidase enzyme to oxidize glucose and transfer electrons to a metal electrode, producing a current. The strength of the current is proportional to the amount of glucose present in the interstitial fluid. The FreeStyle Libre 2 System converts the electrical current signal to a glucose value (in mg/dL) for display on the handheld Reader.

See, e.g., FreeStyle Libre 2 Flash Glucose Monitoring System FDA 510(k) Substantial Equivalence Determination Decision Summary at Pg. 4.

51. The Abbott Libre 2 comprises an electrical contact configured to operably connect the transcutaneous glucose sensor to the sensor electronics.



52. The Abbott Libre 2 comprises a sealing member comprising a sealing member upper portion and a sealing member lower portion, wherein the sealing member at least partially surrounds the electrical contact and at least a portion of the transcutaneous glucose sensor when the transcutaneous glucose sensor is operably connected to the sensor electronics, wherein the sealing member substantially seals at least a portion of the electrical contact from moisture, and wherein an ex vivo portion of the transcutaneous glucose sensor is sandwiched between the sealing member upper portion and the sealing member lower portion.



Living With Your System

Your System can be used during a wide variety of activities.

Activity	What You Need To Know
Bathing, Showering, and Swimming	<p>The Reader is not water-resistant and should NEVER be submerged in water or other liquid. Your Sensor is water-resistant and can be worn while bathing, showering, or swimming.</p> <p>Note: Do NOT take your Sensor deeper than 3 feet (1 meter) or immerse it longer than 30 minutes in water.</p>

See, e.g., User Manual at 99.



54. On information and belief, Abbott, with knowledge of the '452 Patent, and without authority, has actively induced and continues to actively induce infringement by end-users of at least one claim of the '452 Patent, under 35 U.S.C. § 271(b), by intentionally inducing the use, importation, offer for sale, and/or sale of Abbott Libre 2 systems, intending to encourage, and in fact encouraging, end-users to directly infringe the '452 Patent. On information and belief, Abbott actively induced infringement by, *inter alia*, designing and introducing into the stream of commerce the Abbott Libre 2 systems and other infringing CGMs, and by publishing manuals and promotional literature describing and instructing in the operation of the accused devices in an infringing manner and by offering support and technical assistance to its customers that encourage use of the accused products in ways that infringe the asserted claims. In addition, Abbott has had actual knowledge of end users' direct infringement and that Abbott's acts induced such infringement since at least the date of this filing, and when DexCom provided to Abbott a copy of this Complaint.

55. Abbott's infringement has damaged and continues to damage DexCom in an amount yet to be determined, and DexCom will suffer irreparable injury unless the infringement is enjoined by this Court.

COUNT III

Abbott's Infringement of U.S. Patent No. 10,702,215

56. DexCom restates and incorporates by reference all of the allegations made in the preceding paragraphs as though fully set forth herein.

57. DexCom is the owner, by assignment, of U.S. Patent No. 10,702,215, titled “Systems and methods for dynamically and intelligently monitoring a host's glycemic condition after an alert is triggered.” A true and correct copy of the '215 Patent is attached as Exhibit 3.

58. Abbott has infringed, and is continuing to infringe, literally or under the doctrine of equivalents, at least independent claim 19 of the '215 Patent by making, using, selling, and/or offering for sale its Abbott FreeStyle Libre Products, including the FreeStyle Libre 2 with glucose alarms in the United States, in violation of 35 U.S.C. § 271(a). *See, e.g.,* <https://www.freestyle.abbott/us-en/products/freestyle-libre-2.html>.

59. At least as of the filing of the complaint, Abbott has knowledge of the '215 Patent.

60. As a non-limiting example, the Abbott Libre 2 meets the elements of at least claim 19 of the '215 Patent. It is a system for processing data.

The FreeStyle Libre 2 Flash Glucose Monitoring System uses an electrochemical sensor to monitor glucose levels in the interstitial fluid (ISF). The sensor incorporates both the subcutaneously implanted sensor and associated electronics. The sensor uses a glucose oxidase enzyme to oxidize glucose and transfer electrons to a metal electrode, producing a current. The strength of the current is proportional to the amount of glucose present in the interstitial fluid. The FreeStyle Libre 2 System converts the electrical current signal to a glucose value (in mg/dL) for display on the handheld Reader.

See, e.g., FreeStyle Libre 2 Flash Glucose Monitoring System FDA 510(k) Substantial Equivalence Determination Decision Summary at Pg. 4.

61. The Abbott Libre 2 comprises a continuous analyte sensor configured to be implanted within the body.

The FreeStyle Libre 2 Flash Glucose Monitoring System uses an electrochemical sensor to monitor glucose levels in the interstitial fluid (ISF). The sensor incorporates both the subcutaneously implanted sensor and associated electronics. The sensor uses a glucose oxidase enzyme to oxidize glucose and transfer electrons to a metal electrode, producing a current. The strength of the current is proportional to the amount of glucose present in the interstitial fluid. The FreeStyle Libre 2 System converts the electrical current signal to a glucose value (in mg/dL) for display on the handheld Reader.

See, e.g., Id.

62. The Abbott Libre 2 comprises sensor electronics configured to receive and process sensor data output by the sensor.

The FreeStyle Libre 2 Flash Glucose Monitoring System uses an electrochemical sensor to monitor glucose levels in the interstitial fluid (ISF). The sensor incorporates both the subcutaneously implanted sensor and associated electronics. The sensor uses a glucose oxidase enzyme to oxidize glucose and transfer electrons to a metal electrode, producing a current. The strength of the current is proportional to the amount of glucose present in the interstitial fluid. The FreeStyle Libre 2 System converts the electrical current signal to a glucose value (in mg/dL) for display on the handheld Reader.

See, e.g., Id.

63. The Abbott Libre 2 comprises a processor configured to evaluate sensor data using a first function to determine whether a real time glucose value meets one or more user settable first criteria.

The FreeStyle Libre 2 Flash Glucose Monitoring System is a continuous glucose monitoring (CGM) device with real time alarms capability indicated for the management of diabetes in persons age 4 and older. It is intended to replace blood glucose testing for diabetes treatment decisions, unless otherwise indicated.

The System also detects trends and tracks patterns and aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. Interpretation of the System readings should be based on the glucose trends and several sequential readings over time.

See, e.g., Id. at Pg. 2.

System. The Reader does not provide glucose values, arrows, or graph information to users in the absence of a user-initiated action (a sensor scan). The Reader only monitors glucose values in real-time to provide alerts and alarms which, when enabled, warn the user of Low Glucose, High Glucose or Signal Loss and prompt the user to scan the Sensor.

See, e.g., Id. at Pg. 3.

Alerts and Alarms	<p>Low Glucose alarm, High Glucose alarm, signal loss alarm, scan error, sensor error</p> <p>For Low and High Glucose alarms, a user - initiated action is required to see glucose values</p>	<p>Urgent low glucose (55 mg/dL), predictable low glucose, threshold low glucose, threshold high glucose, rising rate of glucose, falling rate of glucose, signal loss, sensor failure, transmitter failure.</p>
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See, e.g., Id. at Pg. 8; *see also* Abbott Libre 2 User's Manual at 56-66.

64. The Abbott Libre 2 comprises a processor configured to evaluate sensor data using a second function to determine whether a parameter indicative of a glucose value meets one or more non-user settable second criteria.

The FreeStyle Libre 2 Flash Glucose Monitoring System is a continuous glucose monitoring (CGM) device with real time alarms capability indicated for the management of diabetes in persons age 4 and older. It is intended to replace blood glucose testing for diabetes treatment decisions, unless otherwise indicated.

The System also detects trends and tracks patterns and aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. Interpretation of the System readings should be based on the glucose trends and several sequential readings over time.

See, e.g., Id. at Pg. 2.

System. The Reader does not provide glucose values, arrows, or graph information to users in the absence of a user-initiated action (a sensor scan). The Reader only monitors glucose values in real-time to provide alerts and alarms which, when enabled, warn the user of Low Glucose, High Glucose or Signal Loss and prompt the user to scan the Sensor.

See, e.g., Id. at Pg. 3.

Alerts and Alarms	<p>Low Glucose alarm, High Glucose alarm, signal loss alarm, scan error, sensor error</p> <p>For Low and High Glucose alarms, a user - initiated action is required to see glucose values</p>	<p>Urgent low glucose (55 mg/dL), predictable low glucose, threshold low glucose, threshold high glucose, rising rate of glucose, falling rate of glucose, signal loss, sensor failure, transmitter failure.</p>
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See, e.g., Id. at Pg. 8; *see also* Abbott Libre 2 User's Manual at 56-66.

65. The Abbott Libre 2 comprises a processor configured to activate a first hypoglycemic indicator if the one or more user settable first criteria is met and activate a second hypoglycemic indicator if the one or more non user settable second criteria are met.

The FreeStyle Libre 2 Flash Glucose Monitoring System is a continuous glucose monitoring (CGM) device with real time alarms capability indicated for the management of diabetes in persons age 4 and older. It is intended to replace blood glucose testing for diabetes treatment decisions, unless otherwise indicated.

The System also detects trends and tracks patterns and aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. Interpretation of the System readings should be based on the glucose trends and several sequential readings over time.

See, e.g., Id. at Pg. 2.

System. The Reader does not provide glucose values, arrows, or graph information to users in the absence of a user-initiated action (a sensor scan). The Reader only monitors glucose values in real-time to provide alerts and alarms which, when enabled, warn the user of Low Glucose, High Glucose or Signal Loss and prompt the user to scan the Sensor.

See, e.g., Id. at Pg. 3.

Alerts and Alarms	Low Glucose alarm, High Glucose alarm, signal loss alarm, scan error, sensor error For Low and High Glucose alarms, a user - initiated action is required to see glucose values	Urgent low glucose (55 mg/dL), predictable low glucose, threshold low glucose, threshold high glucose, rising rate of glucose, falling rate of glucose, signal loss, sensor failure, transmitter failure.
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See, e.g., Id. at Pg. 8; *see also* Abbott Libre 2 User's Manual at 56-66.

66. The Abbott Libre 2 comprises a processor configured to provide an output based on the activated hypoglycemic indicator.

The FreeStyle Libre 2 Flash Glucose Monitoring System is a continuous glucose monitoring (CGM) device with real time alarms capability indicated for the management of diabetes in persons age 4 and older. It is intended to replace blood glucose testing for diabetes treatment decisions, unless otherwise indicated.

The System also detects trends and tracks patterns and aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. Interpretation of the System readings should be based on the glucose trends and several sequential readings over time.

See, e.g., Id. at Pg. 2.

System. The Reader does not provide glucose values, arrows, or graph information to users in the absence of a user-initiated action (a sensor scan). The Reader only monitors glucose values in real-time to provide alerts and alarms which, when enabled, warn the user of Low Glucose, High Glucose or Signal Loss and prompt the user to scan the Sensor.

See, e.g., Id. at Pg. 3.

Alerts and Alarms	Low Glucose alarm, High Glucose alarm, signal loss alarm, scan error, sensor error For Low and High Glucose alarms, a user - initiated action is required to see glucose values	Urgent low glucose (55 mg/dL), predictable low glucose, threshold low glucose, threshold high glucose, rising rate of glucose, falling rate of glucose, signal loss, sensor failure, transmitter failure.
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See, e.g., Id. at Pg. 8; *see also* Abbott Libre 2 User's Manual at 56-66.

67. On information and belief, Abbott, with knowledge of the '215 Patent, and without authority, has actively induced and continues to actively induce infringement by end-users of at least one claim of the '215 Patent, under 35 U.S.C. § 271(b), by intentionally inducing the use, importation, offer for sale, and/or sale of Abbott Libre 2 systems, intending to encourage, and in fact encouraging, end-users to directly infringe the '215 Patent. On information and belief, Abbott actively induced infringement by, *inter alia*, designing and introducing into the stream of commerce the Abbott Libre 2 systems and other infringing glucose monitoring systems, and by publishing manuals and promotional literature describing and instructing in the operation of the accused devices in an infringing manner and by offering support and technical assistance to its customers that encourage use of the accused products in ways that infringe the asserted claims. In addition,

Abbott has had actual knowledge of end users' direct infringement and that Abbott's acts induced such infringement since at least the date of this filing, and when DexCom provided to Abbott a copy of this Complaint.

68. Abbott's infringement has damaged and continues to damage DexCom in an amount yet to be determined, and DexCom will suffer irreparable injury unless the infringement is enjoined by this Court.

COUNT IV

Abbott's Infringement of U.S. Patent No. 10,702,193

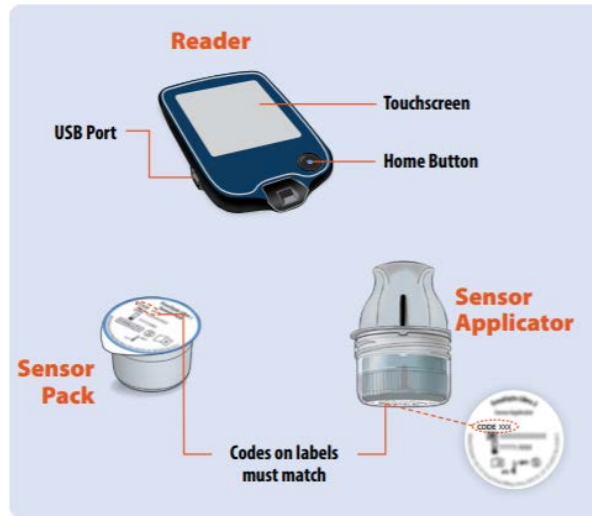
69. DexCom restates and incorporates by reference all of the allegations made in the preceding paragraphs as though fully set forth herein.

70. DexCom is the owner, by assignment, of U.S. Patent No. 10,702,193, titled "Analyte sensing biointerface." A true and correct copy of the '193 Patent is attached as Exhibit 4.

71. Abbott has infringed, and is continuing to infringe, literally or under the doctrine of equivalents, at least independent claim 1 of the '193 Patent by making, using, selling, and/or offering for sale its Abbott FreeStyle Libre Products, including the Libre 2 devices, in the United States in violation of 35 U.S.C. § 271(a). *See, e.g.*, <https://www.diabetescare.abbott/products.html>.

72. At least as of the filing of the complaint, Abbott has knowledge of the '193 Patent.

73. As a non-limiting example, the Abbott Libre 2 is a transcutaneous continuous glucose sensor system.



See, e.g., Abbott Libre 2 User's Manual at 18.

The Sensor measures and stores glucose readings when worn on your body. It initially comes in two parts: one part is in the Sensor Pack and the other part is in the Sensor Applicator. By following the instructions, you prepare and apply the Sensor on the back of your upper arm. The Sensor has a small, flexible tip that is inserted just under the skin. The Sensor can be worn for up to 14 days.

**Sensor**

Measures your glucose while on your body (only visible after applied).

See, e.g., Libre 2 User Manual at 18.

74. The Abbott Libre 2 comprises a substantially planar sensor.



75. The Abbott Libre 2 comprises a first conductive layer associated with a first electrode.

76. The Abbott Libre 2 comprises a first non-conductive layer located at least in part over the first conductive layer.

78. The Abbott Libre 2 comprises a second conductive layer associated with a second electrode, wherein the second conductive layer is located at least in part over the first non-conductive layer.

79. The Abbott Libre 2 comprises a second non-conductive layer located at least in part over the second conductive layer.

80. The Abbott Libre 2 comprises a third conductive layer associated with a third electrode, wherein the third conductive layer is located at least in part over the second non-conductive layer.

81. The Abbott Libre 2 comprises a membrane located over at least a portion of a working electrode.

82. The Abbott Libre 2 includes at least one of the first electrode, the second electrode, or the third electrode is the working electrode, and wherein the working electrode is configured to measure a signal indicative of a glucose concentration.

83. On information and belief, Abbott, with knowledge of the '193 Patent, and without authority, has actively induced and continues to actively induce infringement by end-users of at least one claim of the '193 Patent, under 35 U.S.C. § 271(b), by intentionally inducing the use, importation, offer for sale, and/or sale of Abbott Libre 2 systems, intending to encourage, and in fact encouraging, end-users to directly infringe the '193 Patent. On information and belief, Abbott actively induced infringement by, *inter alia*, designing and introducing into the stream of commerce the Abbott Libre 2 systems and other infringing CGMs, and by publishing manuals and promotional literature describing and instructing in the operation of the accused devices in an infringing manner and by offering support and technical assistance to its customers that encourage use of the accused products in ways that infringe the asserted claims. In addition, Abbott has had actual knowledge of end users' direct infringement and that Abbott's acts induced such infringement since at least the date of this filing, and when DexCom provided to Abbott a copy of this Complaint.

84. Abbott's infringement has damaged and continues to damage DexCom in an amount yet to be determined, and DexCom will suffer irreparable injury unless the infringement is enjoined by this Court.

COUNT V

Abbott's Infringement of U.S. Patent No. 10,993,642

85. DexCom restates and incorporates by reference all of the allegations made in the preceding paragraphs as though fully set forth herein.

86. DexCom is the owner, by assignment, of U.S. Patent No. 10,993,642, titled "Analyte Sensor." A true and correct copy of the '642 Patent is attached as Exhibit 5.

87. Abbott has infringed, and is continuing to infringe, literally or under the doctrine of equivalents, at least independent claim 1 of the '642 Patent by making, using, selling, and/or offering for sale its Abbott FreeStyle Libre Products, including the Libre 2 devices with factory

calibration, in the United States in violation of 35 U.S.C. § 271(a). *See, e.g.*, <https://abbott.mediaroom.com/2017-09-27-No-More-Routine-Finger-Sticks-1-for-Americans-with-Diabetes-Abbott-s-FreeStyle-R-Libre-Approved-in-the-U-S>.

88. At least as of the filing of the complaint, Abbott has knowledge of the '642 Patent.

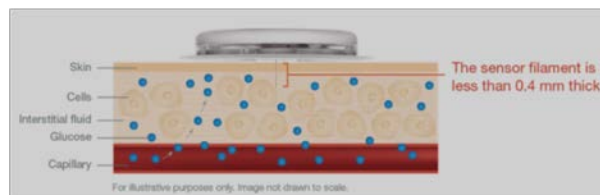
89. As a non-limiting example, the Abbott Libre 2 is a glucose monitoring system that infringes claim 1 of the '642 Patent.

See, e.g., Abbott Libre 2 User's Manual at 18.

90. The Abbott Libre 2 includes a transcutaneous glucose sensor having an in vivo



portion configured to be inserted into a body of a host; and an ex vivo portion configured to remain outside of the body of the host.



See, e.g., <https://www.freestyle.abbott/za/en/benefits-of-cgm.html>.

The Sensor measures and stores glucose readings when worn on your body. It initially comes in two parts: one part is in the Sensor Pack and the other part is in the Sensor Applicator. By following the instructions, you prepare and apply the Sensor on the back of your upper arm. The Sensor has a small, flexible tip that is inserted just under the skin. The Sensor can be worn for up to 14 days.

Sensor
Measures your glucose while on your body (only visible after applied).

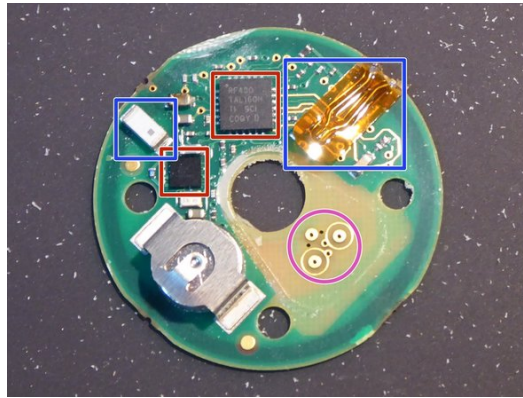


Libre 2 User Manual at 18.

The FreeStyle Libre 2 Flash Glucose Monitoring System uses an electrochemical sensor to monitor glucose levels in the interstitial fluid (ISF). The sensor incorporates both the subcutaneously implanted sensor and associated electronics. The sensor uses a glucose oxidase enzyme to oxidize glucose and transfer electrons to a metal electrode, producing a current. The strength of the current is proportional to the amount of glucose present in the interstitial fluid. The FreeStyle Libre 2 System converts the electrical current signal to a glucose value (in mg/dL) for display on the handheld Reader.

See FreeStyle Libre 2 Flash Glucose Monitoring System FDA 510(k) Substantial Equivalence Determination Decision Summary at Pg. 4.

91. The Abbott Libre 2 includes a processor programmed to calibrate sensor data based at least in part on prior calibration information generated before insertion of the transcutaneous glucose sensor in the host, wherein the sensor data is associated with a glucose concentration of the host, wherein the prior calibration information comprises prior sensitivity information associated with the transcutaneous glucose sensor, wherein the prior calibration information is associated with a sensor code, wherein the sensor code is located in or on a packaging holding the transcutaneous glucose sensor, wherein the processor is programmed to calibrate the sensor data without a need for a reference analyte concentration measurement obtained after insertion of the in vivo portion of the transcutaneous glucose sensor.



Images of the Freestyle Libre 2 processors in the sensor and handheld receiver.



What is Factory Calibration?

Factory calibration of sensors removes the need for determining the sensor sensitivity from the user's responsibility and instead places it in the hands of the sensor manufacturer. The sensor sensitivity is determined during the sensor manufacturing process, and that information is included with every sensor in the form of a sensor code. That code can be preprogrammed into the sensor electronics such that no user interaction is required to enter the code, eliminating the risk of transcription error.

The factory calibration process includes the following steps:

- Manufacture sensor lots with low sensor to sensor variability.
- Sample a number of sensors from each sensor lot and test them in the laboratory (in vitro) for their response to glucose and determine their glucose sensitivity.
- Convert the lot glucose sensitivity into a sensor code.
- Program the sensor code into the sensor electronics memory.
- Demonstrate that the initially determined sensor sensitivity does not change over the sensor shelf life.

Since the variation between the sensors in one sensor lot is small, the laboratory tested sensors are representative of the remaining sensors in the sensor lot, which will be used by patients. The code information provides the necessary sensor sensitivity or calibration factor for every sensor in the sensor lot to convert the electrical sensor current into a glucose value. The determination of the code may include corrections for the difference between in vitro and in vivo sensor testing, which can be determined analytically or empirically through clinical trials, and which can be applied universally to all sensor lots.

This process determines how the sensor responds to glucose and will provide glucose data after sensor insertion without the necessity of a BG test by the user. It does, how-

See, e.g., Factory-Calibrated Continuous Glucose Sensors: The Science Behind the Technology, Udo Hoss at S-45 (annotated); *see also* FreeStyle Libre 2 Flash Glucose Monitoring System FDA 510(k) Substantial Equivalence Determination Decision Summary.

92. On information and belief, Abbott, with knowledge of the '642 Patent, and without authority, has actively induced and continues to actively induce infringement by end-users of at least one claim of the '642 Patent, under 35 U.S.C. § 271(b), by intentionally inducing the use, importation, offer for sale, and/or sale of Abbott Libre 2 systems, intending to encourage, and in fact encouraging, end-users to directly infringe the '642 Patent. On information and belief, Abbott actively induced infringement by, *inter alia*, designing and introducing into the stream of commerce the Abbott Libre 2 systems and other infringing CGMs, and by publishing manuals and promotional literature describing and instructing in the operation of the accused devices in an infringing manner and by offering support and technical assistance to its customers that encourage use of the accused products in ways that infringe the asserted claims. In addition, Abbott has had actual knowledge of end users' direct infringement and that Abbott's acts induced such infringement since at least the date of this filing, and when DexCom provided to Abbott a copy of this Complaint.

93. Abbott's infringement has damaged and continues to damage DexCom in an amount yet to be determined, and DexCom will suffer irreparable injury unless the infringement is enjoined by this Court.

DEMAND FOR JURY TRIAL

Plaintiff demands a jury trial for all issues deemed to be triable by a jury.

PRAYER FOR RELIEF

WHEREFORE, DexCom requests the Court grant the relief set forth below:

A. Enter judgment that Defendants have infringed, and continue to infringe, one or more claims of the '213 Patent, the '452 Patent, the '215 Patent, '193 Patent, and/or the '642 Patent;

B. Temporarily, preliminarily, or permanently enjoin Defendants, their parents, subsidiaries, affiliates, divisions, officers, agents, servants, employees, directors, partners, representatives, all individuals and entities in active concert and/or participation with them, and

all individuals and/or entities within their control from engaging in the aforesaid unlawful acts of patent infringement;

C. Order Defendants to account for and pay damages caused to DexCom by Defendants' unlawful acts of patent infringement in an amount to be proven at trial, together with pre-judgment and post-judgment interest at the maximum rate permitted by law;

D. Award DexCom the interest and costs incurred in this action; and

E. Award DexCom such other and further relief, including equitable relief, as the Court deems just and proper.

DATED: June 30, 2021

Respectfully submitted,

By /s/ Charles Ainsworth

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Attorneys for Plaintiffs

EXHIBIT 3

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT DIABETES CARE INC. and)	
ABBOTT DIABETES CARE LIMITED,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. _____
)	
DEXCOM, INC.,)	JURY TRIAL DEMANDED
)	
Defendant.)	

COMPLAINT

Plaintiffs Abbott Diabetes Care Inc. and Abbott Diabetes Care Limited (collectively “Abbott”), for their Complaint against Defendant Dexcom, Inc. (“Dexcom”), allege as follows:

INTRODUCTION

1. Abbott brings this action to stop Dexcom from infringing multiple Abbott patents protecting Abbott’s award-winning FreeStyle Libre technology, a “life changing” “advance in the management of diabetes.”¹ Diabetes is a chronic condition and global epidemic that affects nearly half a billion people worldwide. Abbott’s innovations make “[r]egular blood sugar monitoring,”

¹ L. Leelarathna & E.G. Wilmot, *Flash forward: a review of flash glucose monitoring*, DIABET. MED., 35(4), 472–482 (2018) (describing FreeStyle Libre as “a watershed moment in the history of diabetes care” and a “significant advance in the management of diabetes” and noting that “[m]any users describe it as ‘life changing’”). FreeStyle Libre has received several awards. These have included the Edison Award as the “best of the best” for “Patient Care” for the first generation FreeStyle Libre system in 2016, and as the “best of the best” for “Personal Wellness Technology” for the second-generation FreeStyle Libre 2 in 2021. *2016 Edison Best New Product Awards™ Winners*, EDISON AWARDS, <https://edisonawards.com/winners2016.php>; *2021 Edison Best New Product Awards™ Winners*, EDISON AWARDS, <https://edisonawards.com/winners2021.php>. In addition, in 2019, FreeStyle Libre was awarded the Prix Galien for “Best Medical Technology.” *The Galien Foundation Honors 2019 Prix Galien Award Recipients*, CISION PR NEWSWIRE <https://www.prnewswire.com/news-releases/the-galien-foundation-honors-2019-prix-galien-award-recipients-300945409.html> (Oct. 25, 2019). “Worldwide, the Prix Galien is regarded as the equivalent of the Nobel Prize in biopharmaceutical and medical technology research.” *Id.*

which is “the most important thing you can do to manage ... diabetes,”² accessible to the world. Were it not for the protections of inventions in the United States Constitution and patent laws, medical technologies that save and improve lives like FreeStyle Libre³ would be unavailable to people who need them. Dexcom’s infringing misconduct is exactly what these laws were designed to protect against, and must be stopped.

2. Diabetes results in blood sugar (glucose) levels that can cause severe health problems such as heart attack, stroke, kidney disease, blindness, amputation, and death. That is why regular blood sugar monitoring is so important for people with diabetes. Historically, monitoring involved “fingerstick” measurements. These required pricking and drawing blood from a finger, putting the blood on a test strip, inserting it into a monitor, and waiting for a test. That method was painful and invasive, and had to be repeated frequently. It also did not show the continuous data that people needed to make more accurate and timely decisions about their

² Center for Disease Control and Prevention, *Monitoring Your Blood Sugar*, CDC.GOV <https://www.cdc.gov/diabetes/managing/managing-blood-sugar/bloodglucosemonitoring.html>.

³ See, e.g., D. Pintus, et al., *Freestyle Libre Flash Glucose Monitoring Improves Patient Quality of Life Measures in Children With Type 1 Diabetes Mellitus (T1DM) With Appropriate Provision of Education and Support by Healthcare Professionals*, DIABETES METAB SYNDR, 13(5), 2923-2926 (Jul. 30, 2019); M. Fokkert, et al., *Improved well-being and decreased disease burden after 1-year use of flash glucose monitoring*, BMJ OPEN DIABETES RESEARCH AND CARE, 2019;7:e000809, doi: 10.1136/bmjdr-2019-000809 (2019); S. Charleer, et al., *Quality of Life and Glucose Control After 1 Year of Nationwide Reimbursement of Intermittently Scanned Continuous Glucose Monitoring in Adults Living With Type 1 Diabetes (FUTURE): A Prospective Observational Real-World Cohort Study*. DIABETES CARE, 43(2):389–397 doi: 10.2337/dc19-1610 (Feb. 2020).

diabetes treatments, diet, and exercise.⁴ Often patients would not do all the fingersticks needed to adequately monitor their glucose levels and prevent the disease's progression and deadly effects.⁵

3. Blood sugar monitoring for diabetes improved with the introduction of continuous glucose monitors. Early continuous glucose monitoring devices, however, were inaccessible and unrealistic for many people with diabetes. They were unaffordable for many, often were not covered by insurance, and required calibration using the same problematic fingersticks they were meant to replace.⁶ They were also bulky, complicated, required separate sensors and transmitters, had gaps in the glucose data they displayed, and required insertion with daunting applicators.

4. Unlike others, Abbott focused its designs on maximizing patient access and convenience, and launched the FreeStyle Libre continuous glucose monitoring system, the first commercially available continuous glucose monitor that avoids fingersticks. FreeStyle Libre made continuous glucose monitoring simple and accessible for a broad population of people with diabetes. Its tiny glucose sensor with integrated electronics is easy to insert, can be discreetly worn for 14 days, and reliably and continuously monitors glucose levels and transmits glucose data to digitally connected devices, including smartphones and dedicated readers. FreeStyle Libre is also much more affordable, often selling for a fraction of the cost of other continuous glucose monitors. Abbott invested enormous resources, including more than a billion dollars, into developing,

⁴ See W. Gonzales, et al., *The Progress of Glucose Monitoring—A Review of Invasive to Minimally and Non-Invasive Techniques, Devices and Sensors*, SENSORS, 19(4):800 doi:10.3390/s19040800 (Feb. 15, 2019) at 1, 5.

⁵ See *id.* at 2, 6.

⁶ See *id.* at 6; see also U. Hoss. & E. Budiman, *Factory-Calibrated Continuous Glucose Sensors: The Science Behind the Technology*, DIABETES TECHNOL. & THER., 19 Supp. 2, S44–S50 (May 1, 2017) doi: 10.1089/dia.2017.0025; D. Rodbard, *Continuous Glucose Monitoring: A Review of Successes, Challenges, and Opportunities*, DIABETES TECHNOL. & THER., 18 Supp. 2, S3–S13 (Feb. 2016) doi: 10.1089/dia.2015.0417; J. Hermanides, et al., *Current Application of Continuous Glucose Monitoring in the Treatment of Diabetes*, DIABETES CARE, 34 Supp. 2, S197–S201 (May 2011) doi: 10.2337/dc11-s219.

building, and expanding the market for FreeStyle Libre. It is now the most accessible and top-selling glucose monitoring system in the world.

5. Dexcom's prior efforts in this space resulted in complex, expensive, and cumbersome devices that failed to achieve the substantial benefits that Abbott's transformative innovations provide. For example, prior generations of Dexcom's CGM devices (including G5) required fingersticks for calibration, had shorter wear times, and required insertion using applicators described by its CEO as "kind of scary"⁷ and likened to an "intimidating" "harpoon."⁸ Now, in its current G6 product, Dexcom has adopted Abbott's patented technologies, including technologies that avoid fingersticks and enable easy insertion, longer wear times, and reliable and continuous transmission of glucose readings to digitally connected devices. But the law does not allow Dexcom to incorporate Abbott's patented technology without authorization and improperly reap the benefits of Abbott's investments.

NATURE OF THE ACTION

6. The Patent Office has awarded Abbott an extensive patent portfolio that protects Abbott's inventions relating to continuous glucose monitoring, including the following: United States Patent Nos. 10,820,842 ("the '842 patent"), 10,827,954 ("the '954 patent"), 10,874,338 ("the '338 patent"), 10,881,341 ("the '341 patent"), 10,945,647 ("the '647 patent"), 10,945,649

⁷ Jonah Comstock, *Dexcom CEO Tells Investors Not to Fear New Competition From Abbott's Freestyle Libre*, MOBI HEALTH NEWS, <https://www.mobihealthnews.com/content/dexcom-ceo-tells-investors-not-fear-new-competition-abbotts-freestyle-libre> (Nov. 8, 2017).

⁸ See, e.g., *Dexcom User Guide for Dexcom G5 Mobile Continuous Glucose Monitoring (CGM) System, Rev 009* MT24706, DEXCOM.COM, <https://s3-us-west-2.amazonaws.com/dexcompdf/G5-Mobile-Users-Guide-Touchscreen-Receiver.pdf>; Jonah Comstock, *Dexcom CEO Tells Investors Not to Fear New Competition From Abbott's Freestyle Libre*, MOBI HEALTH NEWS, <https://www.mobihealthnews.com/content/dexcom-ceo-tells-investors-not-fear-new-competition-abbotts-freestyle-libre> (Nov. 8, 2017); Dana Howe, *Comparing the Dexcom G6 to the G5*, BEYOND TYPE 1, <https://beyondtype1.org/comparing-the-dexcom-g6-to-the-g5/>.

(“the ’649 patent”), 10,952,653 (“the ’653 patent”), 10,959,654 (“the ’654 patent”), 10,966,644 (“the ’644 patent”), 10,973,443 (“the ’443 patent”), 11,000,216 (“the ’216 patent”), and 11,013,440 (“the ’440 patent”) (collectively, the “Asserted Patents”).

7. This is an action for infringement of the Asserted Patents.

8. This action is based on the Patent Laws of the United States, 35 U.S.C. §§ 100, *et seq.*

PARTIES

9. Abbott Diabetes Care Inc. (“ADC Inc.”) is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business in Alameda, California. ADC Inc. holds legal title to the Asserted Patents as the assignee.

10. Abbott Diabetes Care Limited (“ADC Ltd.”) is a company organized under the laws of the United Kingdom, having its principal place of business in Witney, United Kingdom. ADC Ltd. has an exclusive license from ADC Inc. under the Asserted Patents.

11. Dexcom, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business in San Diego, California.

JURISDICTION AND VENUE

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) *et seq.*

13. This Court has personal jurisdiction over Dexcom because, *inter alia*, it is incorporated in Delaware, and thus resides in this District.

14. Venue is proper in this District under 28 U.S.C. § 1400(b) because, *inter alia*, Dexcom is incorporated in Delaware, and thus resides in this District.

BACKGROUND

Diabetes

15. Diabetes is a global epidemic. An estimated 460 million people worldwide have diabetes. By 2045 that number is expected to rise to 700 million.⁹ According to the CDC, in 2020, 26.9 million people were diagnosed with diabetes in the US.¹⁰ Diabetes results in low or high glucose (sugar) levels in the body that can cause severe health problems such as heart attacks, strokes, kidney failure, limb loss, vision loss, and skin ulcers, and can lead to death.¹¹

16. According to the CDC, “[r]egular blood sugar monitoring is the most important thing you can do to manage ... diabetes. You’ll be able to see what makes your numbers go up or down, such as eating different foods, taking your medicine, or being physically active. With this information, you can work with your health care team to make decisions about your best diabetes care plan.”¹²

Prior Blood Glucose Monitoring Methods

17. Traditionally, diabetes patients and healthcare providers monitored blood glucose levels using “fingerstick” methods, often referred to as “self blood glucose monitoring” (“SBGM”), that involved pricking a finger to obtain blood, placing blood on a test strip, and inserting that test strip into a monitor that would give a glucose value. But “[i]t is challenging to

⁹ INTERNATIONAL DIABETES FEDERATION, *IDF Diabetes Atlas* (9th ed. 2019) https://www.diabetesatlas.org/upload/resources/material/20200302_133351_IDFATLAS9e-final-web.pdf.

¹⁰ Center for Disease Control and Prevention, *National Diabetes Statistics Report, 2020*, CDC.GOV, <https://www.cdc.gov/diabetes/data/statistics-report/index.html>.

¹¹ Center for Disease Control and Prevention, *Monitoring Your Blood Sugar*, CDC.GOV, <https://www.cdc.gov/diabetes/managing/managing-blood-sugar/bloodglucosemonitoring.html>.

¹² *Id.*

get more than a limited set” of data from these methods “due to the inconvenience and pain associated with fingersticks, ... and unforgiving requirements for specific timing. Even in the best of circumstances, SBGM data can be challenging to interpret.”¹³ With these traditional methods, patients and providers must frequently extrapolate from a single blood glucose value or from glucose values at scattershot time points without clear temporal relationships to the food, exercise, medication, or other things that affect blood glucose levels — temporal relationships that provide needed context. Further, the fingerstick methods suffered from low compliance, because many patients were so put off by the painful fingersticks that they simply would not test.

18. Various companies developed continuous glucose monitoring products as an alternative to traditional fingerstick measurements. But these products had significant drawbacks including high cost, short wear times, burdensome and painful insertion techniques, non-intuitive operation requiring significant training, and calibration methods requiring regular fingersticks — the painful and invasive sampling that continuous glucose monitor technologies were designed to avoid.¹⁴

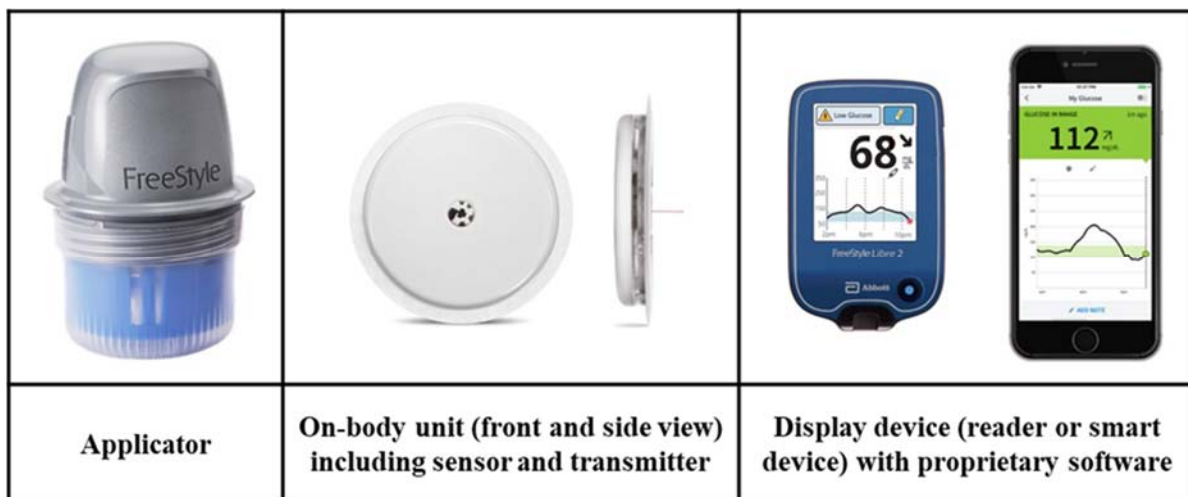
¹³ T. Kompala, et. al, *A New Era: Increasing Continuous Glucose Monitoring Use in Type 2 Diabetes*, AM J. MANG. CARE, 25(4), SP123-SP126 (2019) doi: 10.1111/dme.13149.

¹⁴ See, e.g., W. Gonzales, et al., *The Progress of Glucose Monitoring—A Review of Invasive to Minimally and Non-Invasive Techniques, Devices and Sensors*, SENSORS (BASEL), 2019;19(4):800 at 1 (Feb. 15, 2019) doi: 10.3390/s19040800; U. Hoss. & E. Budiman, *Factory-Calibrated Continuous Glucose Sensors: The Science Behind the Technology*, DIABETES TECHNOL THER , 19 Suppl. 2, S-44–50 (May 1, 2017) doi: 10.1089/dia.2017.0025; D. Rodbard, *Continuous Glucose Monitoring: A Review of Successes, Challenges, and Opportunities*, DIABETES TECHNOL THER., 1; 18 (Suppl 2) S2-3–S2-13 (Feb. 2016) doi: 10.1089/dia.2015.0417; J. Hermanides, M. Phillip & H. DeVries, *Current Application of Continuous Glucose Monitoring in the Treatment of Diabetes*, DIABETES CARE, 34 (Suppl. 2): S197–S201 (May 2011) doi: 10.2337/dc11-s219.

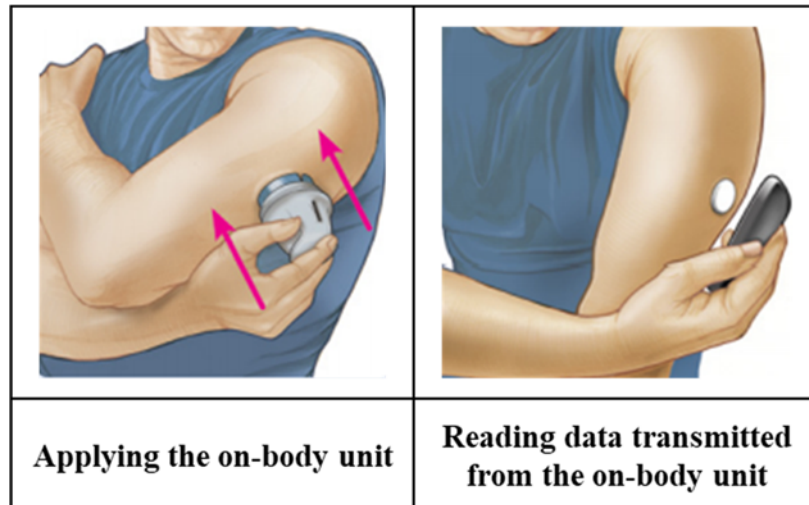
Abbott's FreeStyle Libre Continuous Glucose Monitoring Products

19. In 2014, Abbott introduced the FreeStyle Libre line of continuous glucose monitoring products, which brought new and more accessible technology to the market and addressed problems with prior diabetes and glucose management methods. The original FreeStyle Libre product was first approved for use in Europe in 2014, and in the United States in 2017. Continuing to innovate, Abbott built on these product launches with the FreeStyle Libre 2, which was approved for use in Europe in 2018 and in the United States in 2020, and the FreeStyle Libre 3, which was approved for use in Europe in 2020. These products are referred to herein collectively as the “FreeStyle Libre.”

20. Abbott's FreeStyle Libre includes an applicator, an integrated on-body unit that includes a glucose sensor and a transmitter, and a display device (such as a reader or smart device) with proprietary software (see example below).



21. In a single step, the applicator is used to insert a portion of the glucose sensor under the skin and attach the on-body unit to the user's body with an adhesive patch. Data from the on-body unit is transmitted to a display device where a glucose value and related information are provided to the user.



22. Abbott's FreeStyle Libre overcame significant drawbacks associated with earlier continuous glucose monitoring products. In stark contrast to other glucose monitors in the marketplace, Abbott's FreeStyle Libre eliminated the need for fingerstick calibration by the user to obtain accurate glucose measurements. The FreeStyle Libre is calibrated in the factory, and no fingersticks (or any user-initiated action) are required for calibration.

23. Further, compared to earlier continuous glucose monitoring products, Abbott's FreeStyle Libre offered many other benefits, including:

- significantly lower cost;
- an improved applicator design and process allowing for application of the on-body unit by a user in a single, simple step;
- smaller and less obtrusive device to be positioned on the user's body;
- greater ease-of-use;
- more complete and accurate glucose data; and
- longer wear periods with accurate readings (up to 14 days of continuous use).

These advancements made continuous glucose monitoring products accessible to many people who could not or would not use them previously.

24. Describing FreeStyle Libre, researchers have acknowledged some important advantages: “the [FreeStyle Libre] system is a very easy, painless and user-friendly way of monitoring glucose values without the need for blood. A small sensor is inserted under the skin of one arm and remains there for 14 days. The patient can insert the sensor himself/herself and can replace it with a new sensor when the current one has expired. ... This can be done as often as the patient wishes and in any situation, and is very discreet and fast.”¹⁵

25. Users of FreeStyle Libre often describe how it has changed the way they manage diabetes and improved their lives.

- “[During the first two weeks using FreeStyle Libre,] I learned more about my diabetes and myself ... than I had learned in the previous 15 years. I suddenly had a clearer picture of how my decisions impacted me. I continued to use the product ... and over the next 3 months my A1C¹⁶ dropped from 8.6 to 5.7! The data you get and the ease of getting it makes this an indispensable tool for anyone living with diabetes. I know it changed my life!”¹⁷
- The FreeStyle Libre “has been the easiest and single-most positive ‘medical improvement’ in my diabetic journey since being diagnosed [twenty-two years ago].”¹⁸

¹⁵ L. van den Boom & K. Kostev, *Changes In the Utilization of Blood Glucose Test Strips Among Patients Using Intermittent-Scanning Continuous Glucose Monitoring in Germany*, 22 DIABETES OBES. METAB. 6:922–28 (Jun. 2020) doi: 10.1111/dom.13977.

¹⁶ *A1C Test*, MAYO CLINIC, <https://www.mayoclinic.org/tests-procedures/a1c-test/about/pac-20384643> (The A1C test (also known as the hemoglobin A1C or HbA1c test) is a common blood test used to diagnose diabetes. An A1C test result reflects average blood glucose level for the past two to three months. A1C test results are reported as a percentage. A higher A1C percentage corresponds to higher average blood glucose levels: below 5.7% is normal, 5.7% to 6.4% indicates prediabetes, and 6.5% or higher indicates diabetes. For most adults living with diabetes, an A1C level of less than 7% is a common treatment target).

¹⁷ William M., *Patient Stories*, FREESTYLE LIBRE, <https://www.freestylelibre.us/patient-stories.html>.

¹⁸ NG, *Patient Stories*, FREESTYLE LIBRE, <https://www.freestylelibre.us/patient-stories.html>.

- “I love it and it helps me better understand how and what affects my glucose levels. ... It’s the best thing I could have ever done for my diabetes!!! And the best part—NO MORE PAIN OF FINGER PRICKS!!”¹⁹

26. In 2016, the first-generation FreeStyle Libre was chosen by top senior business executives, academics, and innovation professionals to receive the Edison Award as the “best of the best” for patient care.²⁰ The Edison Awards “recognize[] and honor[] some of the most innovative products ... in the world and [are] among the most prestigious accolades honoring excellence in new product and service development, marketing, design and innovation.”²¹ In April 2021, the FreeStyle Libre 2 received another Edison Award, as “best of the best” for personal wellness technology.²²

27. In 2019, Abbott received the prestigious *Prix Galien* award (the equivalent of the Nobel Prize in biopharmaceutical research), recognizing FreeStyle Libre as the Best Medical Technology approved by the Food and Drug Administration in the prior five years.²³

28. Abbott’s FreeStyle Libre is now the top selling continuous glucose monitoring product in the world. It has helped more than 3 million people across 50 countries by providing breakthrough technology that is affordable, accurate, reliable, and simple to use.

¹⁹ Terri Michelle, *Patient Stories*, FREESTYLE LIBRE, <https://www.freestylelibre.us/patient-stories.html>.

²⁰ *2016 Edison Best New Product Awards™ Winners*, EDISON AWARDS, <https://edisonawards.com/winners2016.php>.

²¹ *About the Edison Awards*, EDISON AWARDS, <https://edisonawards.com/about.php>.

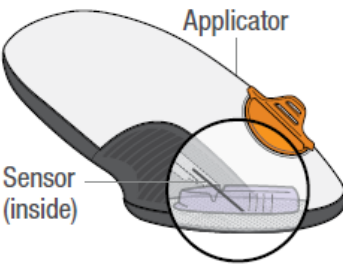
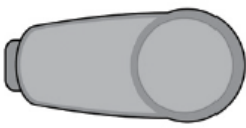

²² *2021 Edison Best New Product Awards™ Winners*, EDISON AWARDS, <https://edisonawards.com/winners2021.php>.

²³ *The Galien Foundation Honors 2019 Prix Galien Award Recipients*, CISION PR NEWswire, <https://www.prnewswire.com/news-releases/the-galien-foundation-honors-2019-prix-galien-award-recipients-300945409.html>. (Oct. 25, 2019).

Dexcom's Follow-On G6 Glucose Monitoring Product

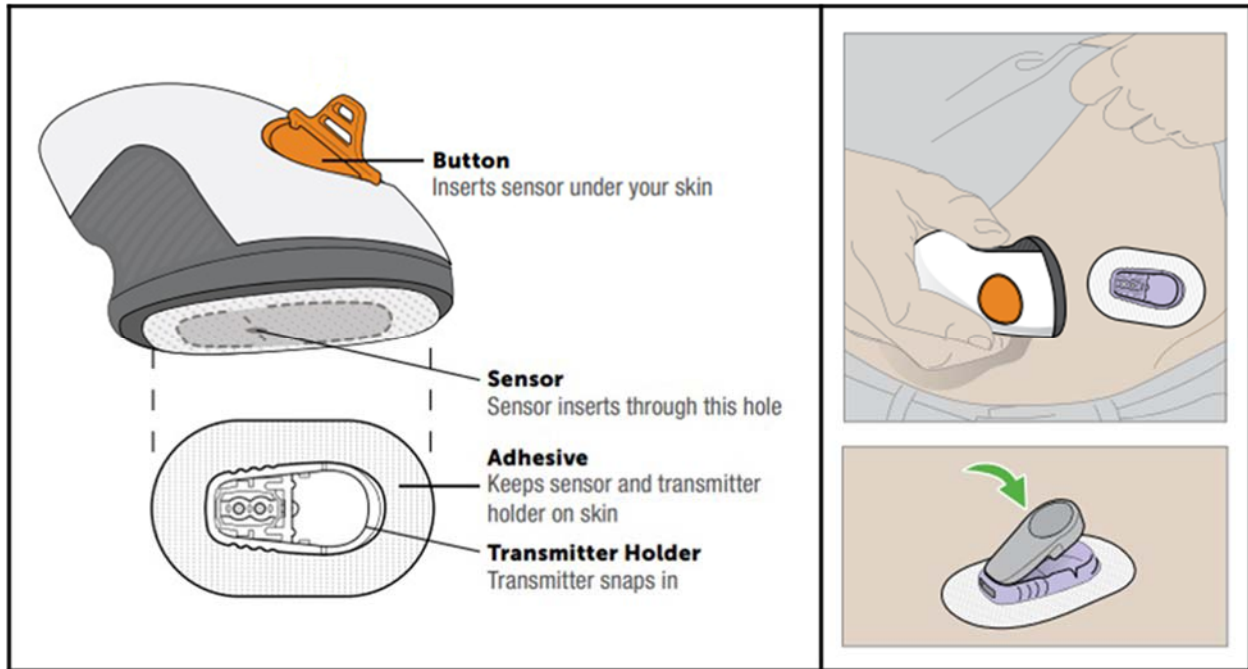
29. In 2018, four years after Abbott first introduced FreeStyle Libre, Dexcom introduced its G6 continuous glucose monitoring product, followed by the G6 Pro in 2020 (collectively the “G6”). Dexcom’s G6, its sixth generation device, is a substantial departure from its fifth generation product (*i.e.*, “G5”) and earlier products. The G6 incorporates many of Abbott’s patented innovations in its design and operation, as illustrated in the attached infringement claim charts.

30. As described by Dexcom in the G6 user guide, the G6 includes three components: an applicator with a sensor, a transmitter, and a display device (receiver or smart device).

What you see	What it's called	What it does
	Applicator with built-in sensor	<p>Applicator helps you insert the sensor wire under your skin.</p> <p>Sensor gets your glucose information.</p>
	Transmitter	Transmitter sends your glucose information from the sensor to the display device.
	<p>Display Device(s):</p> <ul style="list-style-type: none"> • Receiver • Your smart device 	<p>Display device(s) shows your glucose information.</p> <p>Receiver is required for Medicare.</p>

G6 User Guide at 47. As part of G6, Dexcom provides software (*e.g.*, G6 App) for the display devices.

31. As described by Dexcom, the G6 applicator is used, in a single step, to insert a portion of the sensor under the skin and to apply a transmitter holder with an adhesive patch. After the transmitter holder is applied to the skin, the transmitter is snapped into the holder.



G6 User Guide at 77, 80, 83.

32. With G6, Dexcom is using Abbott's breakthrough patented technologies.

33. For example, to obtain accurate readings, all of Dexcom's earlier products required the user to calibrate the product with frequent fingerstick measurements throughout the sensor wear life. But, like Abbott's FreeStyle Libre products, Dexcom's G6 adopts factory calibration, including drift correction to allow for a longer wear period (10 days for G6 versus 7 days for G5), moving away from requiring fingerstick measurements for calibration. Dexcom heavily promotes this feature of its G6 products.²⁴

²⁴ See, e.g., *Better manage your Type 1 or Type 2 diabetes with the Dexcom G6 CGM System*, DEXCOM CONTINUOUS GLUCOSE MONITORING, <https://www.dexcom.com/g6-cgm-system> (The Dexcom G6 "lets you see your glucose and where it's heading without fingersticks.").

34. Likewise, moving away from Dexcom’s “intimidating” and complicated G5 applicator design, the G6 incorporates Abbott’s patented applicator and insertion technologies. Dexcom also promotes these features of its G6 product adopted or resulting from Abbott’s patented technologies.²⁵

35. As evidenced by the substantial departures from the technology in Dexcom’s earlier products, Dexcom is deliberately using Abbott’s patented technology in its G6 product and is infringing Abbott’s valuable patent rights. Abbott is entitled to injunctive relief and to recover damages for such infringement.

ASSERTED PATENTS

36. Abbott has invested heavily in developing and maintaining a portfolio of patents protecting its inventions, including the Asserted Patents.

37. The ’842 patent is titled “Methods and Systems for Early Signal Attenuation Detection and Processing,” and was duly and legally issued on November 3, 2020.

38. A true and correct copy of the ’842 patent is attached as **Exhibit A**.

39. The ’954 patent is titled “Continuous Analyte Measurement Systems and Systems and Methods for Implanting Them,” and was duly and legally issued on November 10, 2020.

40. A true and correct copy of the ’954 patent is attached as **Exhibit B**.

41. The ’338 patent is titled “Devices, Systems and Methods for On-Skin or On-Body Mounting of Medical Devices,” and was duly and legally issued on December 29, 2020.

42. A true and correct copy of the ’338 patent is attached as **Exhibit C**.

²⁵ *Id.* (“Simple auto-applicator – a one-touch applicator easily inserts a small sensor just beneath the skin.”); *id.* (“The Dexcom G6 features a 10-day wear sensor that is ... easy to insert with an auto-applicator.”).

43. The '341 patent is titled "Medical Device Inserters and Processes of Inserting and Using Medical Devices," and was duly and legally issued on January 5, 2021.

44. A true and correct copy of the '341 patent is attached as **Exhibit D**.

45. The '647 patent is titled "Analyte Sensor Transmitter Unit Configuration for a Data Monitoring and Management System," and was duly and legally issued on March 16, 2021.

46. A true and correct copy of the '647 patent is attached as **Exhibit E**.

47. The '649 patent is titled "Medical Device Inserters and Processes of Inserting and Using Medical Devices," and was duly and legally issued on March 16, 2021.

48. A true and correct copy of the '649 patent is attached as **Exhibit F**.

49. The '653 patent is titled "Methods and Systems for Early Signal Attenuation Detection and Processing," and was duly and legally issued on March 23, 2021.

50. A true and correct copy of the '653 patent is attached as **Exhibit G**.

51. The '654 patent is titled "Medical Device Inserters and Processes of Inserting and Using Medical Devices," and was duly and legally issued on March 30, 2021.

52. A true and correct copy of the '654 patent is attached as **Exhibit H**.

53. The '644 patent is titled "Devices, Systems and Methods for On-Skin or On-Body Mounting of Medical Devices," and was duly and legally issued on April 6, 2021.

54. A true and correct copy of the '644 patent is attached as **Exhibit I**.

55. The '443 patent is titled "Sensor Inserter Assembly," and was duly and legally issued on April 13, 2021.

56. A true and correct copy of the '443 patent is attached as **Exhibit J**.

57. The '216 patent is titled "Medical Device Inserters and Processes of Inserting and Using Medical Devices," and was duly and legally issued on May 11, 2021.

58. A true and correct copy of the '216 patent is attached as **Exhibit K**.

59. The '440 patent is titled "Medical Device Inserters and Processes of Inserting and Using Medical Devices," and was duly and legally issued on May 25, 2021.

60. A true and correct copy of the '440 patent is attached as **Exhibit L**.

FIRST CAUSE OF ACTION
(Infringement of the '842 Patent)

61. Abbott repeats and re-alleges the allegations of paragraphs 1 through 60 above.

62. As shown in the claim chart in **Exhibit M**, Dexcom's G6 meets each and every limitation of at least claim 14 of the '842 patent, either literally and/or under the doctrine of equivalents. Thus, Dexcom has infringed and continues to infringe one or more claims of the '842 patent by making, using, selling, and/or offering to sell G6 in the United States and in this District.

63. Unless enjoined by this Court, Dexcom will continue to infringe the '842 patent and as a direct result Abbott will continue to suffer harm, including irreparable harm for which there is no adequate remedy at law. Accordingly, Abbott is entitled to injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

64. Abbott has suffered and will continue to suffer damage as a direct and proximate result of Dexcom's infringement of the '842 patent. Thus, in addition to injunctive relief, Abbott is entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

SECOND CAUSE OF ACTION
(Infringement of the '954 Patent)

65. Abbott repeats and re-alleges the allegations of paragraphs 1 through 64 above.

66. As shown in the claim chart in **Exhibit N**, Dexcom's G6 meets each and every limitation of at least claim 1 of the '954 patent, either literally and/or under the doctrine of

equivalents. Thus, Dexcom has infringed and continues to infringe one or more claims of the '954 patent by making, using, selling, and/or offering to sell G6 in the United States and in this District.

67. Unless enjoined by this Court, Dexcom will continue to infringe the '954 patent and as a direct result Abbott will continue to suffer harm, including irreparable harm for which there is no adequate remedy at law. Accordingly, Abbott is entitled to injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

68. Abbott has suffered and will continue to suffer damage as a direct and proximate result of Dexcom's infringement of the '954 patent. Thus, in addition to injunctive relief, Abbott is entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

THIRD CAUSE OF ACTION
(Infringement of the '338 Patent)

69. Abbott repeats and re-alleges the allegations of paragraphs 1 through 68 above.

70. As shown in the claim chart in **Exhibit O**, Dexcom's G6 meets each and every limitation of at least claim 23 of the '338 patent, either literally and/or under the doctrine of equivalents. Thus, Dexcom has infringed and continues to infringe one or more claims of the '338 patent by making, using, selling, and/or offering to sell G6 in the United States and in this District.

71. Unless enjoined by this Court, Dexcom will continue to infringe the '338 patent and as a direct result Abbott will continue to suffer harm, including irreparable harm for which there is no adequate remedy at law. Accordingly, Abbott is entitled to injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

72. Abbott has suffered and will continue to suffer damage as a direct and proximate result of Dexcom's infringement of the '338 patent. Thus, in addition to injunctive relief, Abbott

is entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

FOURTH CAUSE OF ACTION
(Infringement of the '341 Patent)

73. Abbott repeats and re-alleges the allegations of paragraphs 1 through 72 above.

74. As shown in the claim chart in **Exhibit P**, Dexcom's G6 meets each and every limitation of at least claim 1 of the '341 patent, either literally and/or under the doctrine of equivalents. Thus, Dexcom has infringed and continues to infringe one or more claims of the '341 patent by making, using, selling, and/or offering to sell G6 in the United States and in this District.

75. Unless enjoined by this Court, Dexcom will continue to infringe the '341 patent and as a direct result Abbott will continue to suffer harm, including irreparable harm for which there is no adequate remedy at law. Accordingly, Abbott is entitled to injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

76. Abbott has suffered and will continue to suffer damage as a direct and proximate result of Dexcom's infringement of the '341 patent. Thus, in addition to injunctive relief, Abbott is entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

FIFTH CAUSE OF ACTION
(Infringement of the '647 Patent)

77. Abbott repeats and re-alleges the allegations of paragraphs 1 through 76 above.

78. As shown in the claim chart in **Exhibit Q**, Dexcom's G6 meets each and every limitation of at least claim 1 of the '647 patent, either literally and/or under the doctrine of equivalents. Thus, Dexcom has infringed and continues to infringe one or more claims of the '647 patent by making, using, selling, and/or offering to sell G6 in the United States and in this District.

79. Unless enjoined by this Court, Dexcom will continue to infringe the '647 patent and as a direct result Abbott will continue to suffer harm, including irreparable harm for which there is no adequate remedy at law. Accordingly, Abbott is entitled to injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

80. Abbott has suffered and will continue to suffer damage as a direct and proximate result of Dexcom's infringement of the '647 patent. Thus, in addition to injunctive relief, Abbott is entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

SIXTH CAUSE OF ACTION
(Infringement of the '649 Patent)

81. Abbott repeats and re-alleges the allegations of paragraphs 1 through 80 above.

82. As shown in the claim chart in **Exhibit R**, Dexcom's G6 meets each and every limitation of at least claim 1 of the '649 patent, either literally and/or under the doctrine of equivalents. Thus, Dexcom has infringed and continues to infringe one or more claims of the '649 patent by making, using, selling, and/or offering to sell G6 in the United States and in this District.

83. Unless enjoined by this Court, Dexcom will continue to infringe the '649 patent and as a direct result Abbott will continue to suffer harm, including irreparable harm for which there is no adequate remedy at law. Accordingly, Abbott is entitled to injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

84. Abbott has suffered and will continue to suffer damage as a direct and proximate result of Dexcom's infringement of the '649 patent. Thus, in addition to injunctive relief, Abbott is entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

SEVENTH CAUSE OF ACTION
(Infringement of the '653 Patent)

85. Abbott repeats and re-alleges the allegations of paragraphs 1 through 84 above.

86. As shown in the claim chart in **Exhibit S**, Dexcom's G6 meets each and every limitation of at least claim 1 of the '653 patent, either literally and/or under the doctrine of equivalents. Thus, Dexcom has infringed and continues to infringe one or more claims of the '653 patent by making, using, selling, and/or offering to sell G6 in the United States and in this District.

87. Unless enjoined by this Court, Dexcom will continue to infringe the '653 patent and as a direct result Abbott will continue to suffer harm, including irreparable harm for which there is no adequate remedy at law. Accordingly, Abbott is entitled to injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

88. Abbott has suffered and will continue to suffer damage as a direct and proximate result of Dexcom's infringement of the '653 patent. Thus, in addition to injunctive relief, Abbott is entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

EIGHTH CAUSE OF ACTION
(Infringement of the '654 Patent)

89. Abbott repeats and re-alleges the allegations of paragraphs 1 through 88 above.

90. As shown in the claim chart in **Exhibit T**, Dexcom's G6 meets each and every limitation of at least claim 1 of the '654 patent, either literally and/or under the doctrine of equivalents. Thus, Dexcom has infringed and continues to infringe one or more claims of the '654 patent by making, using, selling, and/or offering to sell G6 in the United States and in this District.

91. Unless enjoined by this Court, Dexcom will continue to infringe the '654 patent and as a direct result Abbott will continue to suffer harm, including irreparable harm for which

there is no adequate remedy at law. Accordingly, Abbott is entitled to injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

92. Abbott has suffered and will continue to suffer damage as a direct and proximate result of Dexcom's infringement of the '654 patent. Thus, in addition to injunctive relief, Abbott is entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

NINTH CAUSE OF ACTION
(Infringement of the '644 Patent)

93. Abbott repeats and re-alleges the allegations of paragraphs 1 through 92 above.

94. As shown in the claim chart in **Exhibit U**, Dexcom's G6 meets each and every limitation of at least claim 1 of the '644 patent, either literally and/or under the doctrine of equivalents. Thus, Dexcom has infringed and continues to infringe one or more claims of the '644 patent by making, using, selling, and/or offering to sell G6 in the United States and in this District.

95. Unless enjoined by this Court, Dexcom will continue to infringe the '644 patent and as a direct result Abbott will continue to suffer harm, including irreparable harm for which there is no adequate remedy at law. Accordingly, Abbott is entitled to injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

96. Abbott has suffered and will continue to suffer damage as a direct and proximate result of Dexcom's infringement of the '644 patent. Thus, in addition to injunctive relief, Abbott is entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

TENTH CAUSE OF ACTION
(Infringement of the '443 Patent)

97. Abbott repeats and re-alleges the allegations of paragraphs 1 through 96 above.

98. As shown in the claim chart in **Exhibit V**, Dexcom's G6 meets each and every limitation of at least claim 13 of the '443 patent, either literally and/or under the doctrine of equivalents. Thus, Dexcom has infringed and continues to infringe one or more claims of the '443 patent by making, using, selling, and/or offering to sell G6 in the United States and in this District.

99. Unless enjoined by this Court, Dexcom will continue to infringe the '443 patent and as a direct result Abbott will continue to suffer harm, including irreparable harm for which there is no adequate remedy at law. Accordingly, Abbott is entitled to injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

100. Abbott has suffered and will continue to suffer damage as a direct and proximate result of Dexcom's infringement of the '443 patent. Thus, in addition to injunctive relief, Abbott is entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

ELEVENTH CAUSE OF ACTION
(Infringement of the '216 Patent)

101. Abbott repeats and re-alleges the allegations of paragraphs 1 through 100 above.

102. As shown in the claim chart in **Exhibit W**, Dexcom's G6 meets each and every limitation of at least claim 1 of the '216 patent, either literally and/or under the doctrine of equivalents. Thus, Dexcom has infringed and continues to infringe one or more claims of the '216 patent by making, using, selling, and/or offering to sell G6 in the United States and in this District.

103. Unless enjoined by this Court, Dexcom will continue to infringe the '216 patent and as a direct result Abbott will continue to suffer harm, including irreparable harm for which there is no adequate remedy at law. Accordingly, Abbott is entitled to injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

104. Abbott has suffered and will continue to suffer damage as a direct and proximate result of Dexcom's infringement of the '216 patent. Thus, in addition to injunctive relief, Abbott is entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

TWELFTH CAUSE OF ACTION
(Infringement of the '440 Patent)

105. Abbott repeats and re-alleges the allegations of paragraphs 1 through 104 above.

106. As shown in the claim chart in **Exhibit X**, Dexcom's G6 meets each and every limitation of at least claim 1 of the '440 patent, either literally and/or under the doctrine of equivalents. Thus, Dexcom has infringed and continues to infringe one or more claims of the '440 patent by making, using, selling, and/or offering to sell G6 in the United States and in this District.

107. Unless enjoined by this Court, Dexcom will continue to infringe the '440 patent and as a direct result Abbott will continue to suffer harm, including irreparable harm for which there is no adequate remedy at law. Accordingly, Abbott is entitled to injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

108. Abbott has suffered and will continue to suffer damage as a direct and proximate result of Dexcom's infringement of the '440 patent. Thus, in addition to injunctive relief, Abbott is entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

PRAYER FOR RELIEF

WHEREFORE, Abbott prays for the following relief:

a. a judgment that Dexcom has infringed and is infringing each of the Asserted Patents;

b. an order permanently enjoining Dexcom, its officers, agents, servants, employees and attorneys, all parent, subsidiary, and affiliate corporations and other related business entities, and all other persons or entities acting in concert, participation or in privity with one or more of them, and their successors and assigns, from infringing the Asserted Patents;

c. a judgment against Dexcom for money damages sustained as a result of Dexcom's infringement of the Asserted Patents in an amount to be determined at trial as provided under 35 U.S.C. § 284;

d. an award of pre-judgment and post-judgment interest on the damages caused by Dexcom's infringing activities and other conduct complained of herein;

e. a finding that this case is an exceptional case under 35 U.S.C. § 285;

f. a judgment awarding Abbott reasonable attorneys' fees and its costs and reimbursements in this action, as provided by 35 U.S.C. § 285;

g. an accounting for infringing sales not presented at trial and an award by the Court of additional damages for any such infringing sales;

h. a compulsory future royalty; and

i. any and all other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Abbott hereby respectfully requests trial by jury under Rule 38 of the Federal Rules of Civil Procedure of all issues in this action so triable.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

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EXHIBIT 4

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Date
13 July 2021

Our reference
UNMS/UMCR/ABB60.U30

Your reference

Dear Sir or Madam

**Abbott Diabetes Care Inc., Abbott Laboratories Vascular Enterprises LP, Abbott Ireland,
Abbott Diabetes Care Limited, Abbott Diagnostics GmbH and Abbott Laboratories Limited
v Dexcom Incorporated, Dexcom International Limited, Dexcom Operating Limited and
Dexcom (UK) Distribution Limited – HP-2021-000025**

We are writing to notify you of the proceedings served at the UK registered addresses of Dexcom Operating Limited and Dexcom (UK) Distribution Limited yesterday, 12 July 2021.

For information, we enclose the following documents:

1. Letter of service dated 12 July 2021;
2. Claim form;
3. Particulars of Claim; and
4. Particulars of Infringement.

Yours faithfully

Taylor Wessing LLP

Taylor Wessing LLP

Taylor Wessing LLP is a limited liability partnership registered in England and Wales, registered number OC322935. A list of members is available for inspection at our registered office: 5 New Street Square, London EC4A 3TW.

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Taylor Wessing is the trading name used by a number of distinct legal entities. Further information can be found on our regulatory page at www.taylorwessing.com

Claim No. HP-2021-000025

IN THE HIGH COURT OF JUSTICE
BUSINESS AND PROPERTY COURTS OF ENGLAND & WALES
INTELLECTUAL PROPERTY LIST (ChD)
PATENTS COURT

BETWEEN:

- 1) ABBOTT DIABETES CARE INC.
(a company incorporated under the laws of Delaware, U.S.A.)
- 2) ABBOTT LABORATORIES VASCULAR ENTERPRISES LP
(a limited partnership formed under the laws of Ireland)
- 3) ABBOTT IRELAND
(a company incorporated under the laws of Bermuda)
- 4) ABBOTT DIABETES CARE LIMITED
- 5) ABBOTT DIAGNOSTICS GMBH
(a company incorporated under the laws of Germany)
- 6) ABBOTT LABORATORIES LIMITED

Claimants

and

- 1) DEXCOM, INC.
(a company formed under the laws of the state of Delaware, U.S.A.)
- 2) DEXCOM INTERNATIONAL LIMITED
(a company formed under the laws of Cyprus)
- 3) DEXCOM OPERATING LIMITED
- 4) DEXCOM (UK) DISTRIBUTION LIMITED

Defendants

PARTICULARS OF CLAIM

1. The First Claimant is part of the Abbott Laboratories group of companies ("**Abbott**"), a leading global healthcare group. The First Claimant is the registered proprietor of the following patents (collectively referred to as "**the Patents**"):
 - a) European Patent (UK) 2 146 625 ("**the 625 Patent**");
 - b) European Patent (UK) 2 146 627 ("**the 627 Patent**");
 - c) European Patent (UK) 2 280 636 ("**the 636 Patent**");

- d) European Patent (UK) 2 393 418 ("**the 418 Patent**");
 - e) European Patent (UK) 2 476 223 ("**the 223 Patent**");
 - f) European Patent (UK) 2 549 918 ("**the 918 Patent**");
 - g) European Patent (UK) 3 087 771 ("**the 771 Patent**"); and
 - h) European Patent (UK) 3 494 882 ("**the 882 Patent**").
2. The Second Claimant is the exclusive licensee of the Patents for all countries of the world except for the United States and Puerto Rico in respect of the right to develop, make, have made, import, export, market, offer for sale, sell, have sold, otherwise dispose of, use and keep, whether for disposal or otherwise continuous glucose monitoring products and related products (together, "**CGM-Related Products**").
 3. The Third Claimant is the exclusive sub-licensee of the Second Claimant for all countries of the world except for the United States and Puerto Rico in respect of the right to make CGM-Related Products and in respect of the right to dispose of, offer to dispose of and keep CGM-Related Products for supply to the Fifth Claimant.
 4. The Fourth Claimant is the exclusive sub-licensee of the Third Claimant for the United Kingdom in respect of the right to make CGM-Related Products.
 5. The Fifth Claimant is the exclusive sub-licensee of the Second Claimant for all countries of the world except for the United States and Puerto Rico in respect of the right to market, offer for sale, sell, have sold, otherwise dispose of, use and keep, whether for disposal or otherwise, CGM-Related Products only for the purposes of supply to local Abbott affiliates that sell CGM-Related Products in various countries.
 6. The Sixth Claimant is the exclusive sub-licensee of the Second Claimant for the United Kingdom in respect of the right to import, market, offer for sale, sell, have sold, otherwise dispose of, use and keep, whether for disposal or otherwise, CGM-Related Products to third party customers.
 7. The Patents are and have at all material times been in force in the UK.
 8. The First Defendant is a company incorporated in the state of Delaware, USA and with headquarters in San Diego, California, U.S.A.
 9. The Second Defendant is a Cyprus company with a registered establishment in the United Kingdom and a subsidiary of the First Defendant. The Third and Fourth

Defendants are subsidiaries of the First Defendant that carry out business in the United Kingdom.

10. The Defendants (collectively, "**Dexcom**") develop, manufacture, distribute and sell continuous glucose monitoring systems for diabetes management, including the Dexcom G6 continuous glucose monitoring system ("**the G6 Device**"). From a date unknown to the Claimants, but to the best of their knowledge and belief during 2021, the Defendants intend to manufacture, distribute and sell the Dexcom G7 continuous glucose monitoring system ("**the G7 Device**").
11. The Defendants and any or each of them have infringed and/or are threatening to infringe the Patents and each of them as set out in the Particulars of Infringement served herewith.
12. By reason of the matters complained of, the Claimants and each of them are suffering loss and damage. Unless the Defendants are restrained by the Court, the Claimants will suffer further loss and damage.
13. The Claimants are not at present able to give particulars of all of each Defendant's acts of infringement but the Claimants will seek relief in respect of any such act at trial.
14. The Claimants are entitled to and claim interest on all sums found due to them pursuant to section 35A of the Senior Courts Act 1981 or the equitable jurisdiction of the Court at such rate and for such a period as the Court sees fit.

AND THE CLAIMANTS CLAIM:

- (1) A declaration that the Patents and each of them are infringed by the Defendants' actions with respect to the G6 Device and/or would be infringed by the Defendants' intended actions with respect to the G7 Device.
- (2) An injunction to restrain the Defendants and any or each of them (whether acting by themselves or through directors, officers, agents, third parties or any of them otherwise howsoever) from infringing the Patents or each of them.
- (3) An order for delivery up or destruction upon oath of all articles and materials in the possession, custody or control of the Defendants and any or each of them, the use of which would constitute a breach of the aforesaid injunction.
- (4) An order for appropriate measures for the dissemination and publication of the judgment and order to be taken at the expense of the Defendants and any or each of them.

- (5) An inquiry as to damages or, at the Claimants' election, an account of profits in respect of each and every act of infringement of the Patents occurring on or after 1 April 2021.
- (6) An order that the Defendants and any or each of them pay the Claimants all sums found due together with interest pursuant to the Court's equitable jurisdiction for such period and at such rate as the Court sees fit.
- (7) Costs, together with interest on costs.
- (8) Further or other relief.

THOMAS MITCHESON QC

TIM AUSTEN

GEORGINA MESSENGER

STATEMENT OF TRUTH

The Claimants believe the facts stated in these Particulars of Claim are true. I am duly authorised by the Claimants to sign this statement on their behalf. The Claimants understand that proceedings for contempt of court may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief in its truth.

Signed:



Name: Nigel Martin Stoate

Position: Partner, Taylor Wessing LLP

SERVED THIS 12 day of July 2021 by Taylor Wessing LLP of 5 New Street Square, London EC4A 3TW, DX41 London, Solicitors for the Claimants

Claim No. HP-2021-000025

IN THE HIGH COURT OF JUSTICE
BUSINESS AND PROPERTY COURTS OF ENGLAND & WALES
INTELLECTUAL PROPERTY LIST (ChD)
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BETWEEN:

- 1) ABBOTT DIABETES CARE INC.
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Claimants

and

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- 2) DEXCOM INTERNATIONAL LIMITED
(a company formed under the laws of Cyprus)
- 3) DEXCOM OPERATING LIMITED
- 4) DEXCOM (UK) DISTRIBUTION LIMITED

Defendants

PARTICULARS OF INFRINGEMENT

1. These are the Particulars of Infringement of the Patents referred to in the Particulars of Claim herein. References to the Particulars of Claim include any subsequent amended Particulars of Claim. Unless otherwise defined herein, the Claimants adopt the definitions used in the Particulars of Claim served herewith.
2. On or after 1 April 2021 the Defendants and any or each of them have offered to dispose of, disposed of, used, imported and kept the Dexcom G6 continuous glucose monitoring system ("**the G6 Device**") in the United Kingdom. In these Particulars of Infringement, the term "G6 Device" shall include all versions of the device referred to

consumer and Dexcom, and include Dexcom's international subsidiaries, *inter alia* the Second, Third and Fourth Defendants.

- (6) User guides for the Dexcom G6 Device, available for download from the Website at the domain: <https://www.dexcom.com/en-GB/downloadsandguides/search>. Copies of which are enclosed at Annex 5 hereto.
3. The G6 Device comprises three main components: a sensor, a Bluetooth Low Energy transmitter and a display device (being a handheld receiver or a mobile application for a smartphone). The sensor is for the measurement of interstitial glucose levels in a user. The sensor component consists of an applicator, a plastic base and a sensor probe, and the applicator (sometimes known as an inserter) is used to insert the sensor under the user's skin. The transmitter component attaches to the sensor, and contains a Bluetooth radio transceiver for communication with the compatible display device. The display device may be a handheld receiver supplied by Dexcom, or the user's smartphone which is set up to operate an application provided by Dexcom and which can be downloaded by the user.
4. In order to begin operating the sensor, and pair the sensor device to the transmitter and the display device, the user must enter the transmitter ID number into the display device. The user must also enter the sensor code, which permits calibration of the sensor on the basis of factory calibration steps carried out upon manufacture. Alternatively, calibration of the sensor may be carried out manually on the basis of fingerstick glucose readings. In operation, the relevant display device displays *inter alia* a current glucose reading and glucose trends to the user, may be configured to provide alarms and indications as necessary, and also alerts the user if *inter alia* the signal from the sensor is lost, or if the sensor has expired.
5. Further particulars of the nature and operation of the G6 Device are found in the G6 Device user guides, referred to at paragraph 2(6) above, and in the Clinical Evaluation Report for the Dexcom Continuous Glucose Monitoring Systems dated 18 January 2018, available on the website of the Czech medical device regulator, Sukl, at <https://www.sukl.cz/modules/delivery//file.php?id=366031072> (a copy of which is enclosed at Annex 6 hereto). It is to be reasonably inferred that such documents describe the nature and operation of the G6 Device as it is offered for sale and sold in the United Kingdom.
6. From a date unknown to the Claimants, but to the best of their knowledge and belief during 2021, the Defendants and any or each of them are intending to offer, offer to

- (6) The Defendants describe the G7 Device as a "next generation" to the G6 Device. For example, the US SEC Form 10-K referred to above (Annex 4) indicates that the Defendants are "*pursuing regulatory approvals for our next generation G7 CGM system*". It can therefore reasonably be inferred that the G7 Device will be manufactured and marketed in the same manner as the G6 Device and that the Defendants will offer, offer to dispose of, dispose, use, import and keep the G7 Device in the same way that they have the G6 Device. Further, it is a reasonable inference that the Defendants will seek to offer the G7 Device to users of the G6 Device in the United Kingdom by way of upgrade on the existing product. In this respect paragraph 2 herein, and the subparagraphs thereto, are repeated.
- (7) Further, it is a reasonable inference that the G7 Device will be marketed through the Dexcom Website. Paragraph 2(5) herein is repeated.

7. Although the G7 Device is expected to include additional new features and functions and improvements to the existing features and functions of the G6 Device, to the Claimants' knowledge and belief the material functions of the G6 Device will also be included in and/or utilised by the G7 Device but the G7 Device will differ from the G6 Device in that the wearable portion of the G7 Device will have the sensor and transmitter combined into a single, disposable wearable.

PARTICULARS

- (1) The US SEC Form 10-K for the First Defendant for fiscal year ended 31 December 2020 (Annex 4) states "*the G7 carries forward many of the same features as our G6 CGM system and adds several new or improved features*".
- (2) The new features identified in the US SEC Form 10-K are as follows:
- **Reduced size.** A 60% reduction in size of the on-body wearable.
 - **Fully disposable.** Sensor and transmitter combined into a single, disposable wearable.
 - **Simple application.** New application process streamlines the number of steps required.
 - **Faster warmup.** Warmup period expected to be reduced from the current two-hour warmup for G6.
 - **Reduced packaging waste.** Significant reduction to the product packaging waste profile on a per unit basis."
- (3) In the presentation at the JPM Healthcare Conference referred to above Mr Sayer indicated that the Defendants were scaling up automated manufacturing of G7 in expectation of a rapid switch from G6 to G7. If the Defendants expect consumers and/or the market to make a rapid switch from the G6 Device to the

18 of the 636 Patent, of at least claims 1 and 8 of the 771 Patent, of at least claim 1 of the 223 Patent, of at least claim 1 of the 418 Patent and of at least claim 9 of the 918 Patent, knowing, or it being obvious to a reasonable person in the circumstances, that those means are suitable for putting, and are intended to put, the invention into effect in the United Kingdom.

10. In relation to paragraph 9(a) above, the G6 Device constitutes or comprises, and the G7 Device will constitute or comprise, a product within at least claim 7 of the 625 Patent, at least claim 8 of the 627 Patent, at least claim 1 of the 882 Patent, and at least claim 18 of the 636 Patent, and the G7 Device will constitute or comprise a product within at least claim 1 of the 418 Patent and at least claim 1 of the 918 Patent.
11. In relation to paragraph 9(b) above, the use of the G6 Device by end users constitutes or comprises, and use of the G7 Device will constitute or comprise, the use of the method within at least claim 1 of the 625 Patent, within at least claim 1 of the 627 Patent, within at least claim 1 of the 636 Patent, within at least claims 1 and 8 of the 771 Patent, and within at least claim 1 of the 223 Patent, and use of the G7 Device will constitute or comprise the use of the method within at least claim 9 of the 918 Patent.
12. The Defendants know, or it is obvious to the reasonable person in the circumstances, that the method of operation of the G6 and/or G7 Devices by end users would be an infringement of the 625 Patent, the 627 Patent, the 636 Patent, the 771 Patent, the 223 Patent and of the 918 Patent.

PARTICULARS OF KNOWLEDGE

Pending admissions, further information and/or disclosure, the Claimants will rely on the following:

- (1) The Defendants have considerable expertise in the design, manufacture and marketing of continuous glucose monitoring systems and, in the premises, knew or ought to know how the G6 and/or G7 Devices operate;
- (2) Further, the Defendants and their group of companies, as a large international manufacturer of continuous glucose monitoring systems, will have at all material times monitored patents granted to its competitors in the same field, including those granted to the First Claimant. Alternatively, it was reasonable to expect the Defendants to have carried out such monitoring. Therefore, the Defendants are and were at all material times aware of the 625 Patent, the 627 Patent, the 636 Patent, the 771 Patent, the 223 Patent and the 918 Patent, and that the marketing and sale of the G6 Device in the United Kingdom infringed

JOINT TORTFEASANCE OF THE DEFENDANTS

16. The Defendants and each of them have committed the acts complained of herein pursuant to a common design and/or have aided and abetted, counselled or procured the commission of such acts by each other such that they are jointly and severally liable for such acts as joint tortfeasors thereof. The common objective of all the various facts and matters pleaded above is to market the G6 and/or G7 Devices in the United Kingdom.
17. In support of the foregoing but without prejudice to the generality of the same, the Claimants will rely upon the following:
- (a) The Defendants are members of the same corporate group of companies, operating jointly under the brand "Dexcom", and are in the business of *inter alia* manufacturing, importing, marketing and supplying the G6 and/or G7 Devices;
 - (b) The First Defendant is the parent company of the Dexcom group of companies and is responsible for the direction of the corporate group and ultimately responsible for the acts carried out and the products sold by the Dexcom business;
 - (c) In its Annual Report Form 10-K for the year ended 31 December 2020 available at <https://investors.dexcom.com/node/20456/html>, the First Defendant stated:

Commercial Operations

We have built a direct sales organization in the United States, Canada and certain countries in Europe to call on health care professionals, such as endocrinologists, physicians and diabetes educators, who can educate and influence patient adoption of continuous glucose monitoring. ... We directly market our products in the United States, Austria, Canada, Germany, Ireland, Switzerland, and the United Kingdom primarily to endocrinologists, physicians and diabetes educators. (p.10)

Our operations in countries outside the United States, which accounted for approximately 22% of our revenues for the twelve months ended December 31, 2020, are accompanied by certain financial and other risks. In addition to opening offices in Austria, Canada, Germany, the Philippines, Switzerland and the United Kingdom, in connection with distributor acquisitions and otherwise, we intend to continue to pursue growth opportunities in sales outside the United States, especially in Asia (including Japan and Korea) and Europe, and we may increase our use of administrative and support functions from locations outside the United States, which could expose us to greater risks associated with our sales and operations. (p.33)

Name: Nigel Martin Stoate

Position: Partner, Taylor Wessing LLP

SERVED THIS 12 day of July 2021 by Taylor Wessing LLP of 5 New Street Square, London
EC4A 3TW, DX41 London, Solicitors for the Claimants

TaylorWessing

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San Diego,
CA 92121
USA

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1 Tanfield,
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DEXCOM (UK) DISTRIBUTION LIMITED
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Date
12 July 2021

Our reference
UNMS/UMCR/ABB60.U30

Your reference

Dear Sir or Madam

Abbott Diabetes Care Inc. and others v Dexcom Inc. and others HP-2021-000025

We enclose by way of service, and for Dexcom Inc. for information, a copy of proceedings issued earlier today by our clients alleging infringement by your G6 and forthcoming G7 products of EP (UK) 2 146 625, EP (UK) 2 146 627, EP (UK) 3 494 882, EP (UK) 2 393 418, EP (UK) 2 280 636, EP (UK) 3 087 771, EP (UK) 2 476 223, and EP (UK) 2 549 918 (the "**Patents in Suit**").

Please let us know by return the identity of your UK solicitors and confirm that they are instructed to accept service on behalf of Dexcom Inc.

As you will see, the allegations of infringement by the G7 product are brought on a *quia timet* basis. We understand from public pronouncements that you intend to launch the G7 product in the European market towards the end of 2021. Please confirm the UK launch date.

We also understand that, unlike your G6 product, your G7 product will comprise a fully disposable device with integrated electronics. We therefore invite you to provide forthwith full details of your G7 product (which can be handled under a suitable confidentiality regime, if appropriate) so the parties can assess fully the issues of infringement at the earliest opportunity.

Taylor Wessing LLP is a limited liability partnership registered in England and Wales, registered number OC322935. A list of members is available for inspection at our registered office: 5 New Street Square, London EC4A 3TW.

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UKMATTERS:62367699.1

2

Our clients confirm according to PD51U paragraph 4.5 that steps have been taken to preserve relevant documents in accordance with PD51U paragraphs 3.1(1) and 3.2(1).

In the meantime, our clients reserve all their rights.

Yours faithfully

Taylor Wessing LLP

Taylor Wessing LLP



Claim Form

IN THE HIGH COURT OF JUSTICE
 BUSINESS & PROPERTY COURTS
 OF ENGLAND & WALES
 12 Jul 2021
 INTELLECTUAL PROPERTY LIST (ChD)
 PATENTS COURT

HP-2021-000025

	for court use only
Claim No.	
Issue date	

Claimants

- (1) ABBOTT DIABETES CARE INC.
 - (2) ABBOTT LABORATORIES VASCULAR ENTERPRISES LP
 - (3) ABBOTT IRELAND
 - (4) ABBOTT DIABETES CARE LIMITED
 - (5) ABBOTT DIAGNOSTICS GMBH
 - (6) ABBOTT LABORATORIES LIMITED
- (see attached Schedule of Claimants' addresses)

Defendants

- (1) DEXCOM INCORPORATED
- (2) DEXCOM INTERNATIONAL LIMITED
- (3) DEXCOM OPERATING LIMITED
- (4) DEXCOM (UK) DISTRIBUTION LIMITED

Brief details of claim

See overleaf

Value

The estimated value of the Claim exceeds £10,000,000.

This is an Intellectual Property claim and in the normal course will proceed by way of split trial with liability being dealt with first. The Claimant will not be able to elect between damages or an account of profits until liability has been established. As such the remedy sought comprises non-money relief. The Claimant undertakes to pay any additional court fee as directed by the court at the appropriate time if liability is established and monetary relief is elected.

The claim must be heard in a specialist list, the Patents Court list, in accordance with Part 63 of the Civil Procedure Rules

Defendants' names and addresses for service including postcode

See attached Schedule of Defendants' addresses

	£
Amount claimed	Unspecified
Court Fee	528.00
Legal representative's costs	To be assessed
Total amount	Unspecified

Brief Details of Claim

Claim No.	
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The Claimants' claim is for:

- (1) A declaration that patents EP (UK) 2 146 625, EP (UK) 2 146 627, EP (UK) 2 280 636, EP (UK) 2 393 418, EP (UK) 2 476 223, EP (UK) 2 549 918, EP (UK) 3 087 771 and EP (UK) 3 494 882 ("the Patents") and each of them are infringed by the Defendants' actions with respect to Dexcom's G6 Continuous Glucose Monitoring System and/or the Defendants' intended actions with respect to Dexcom's G7 Continuous Glucose Monitoring System.
- (2) An injunction to restrain the Defendants (whether acting by themselves or through directors, officers, agents, third parties or any of them otherwise howsoever) from infringing the Patents or each of them.
- (3) An order for delivery up or destruction upon oath of all articles and materials in the possession, custody or control of the Defendants, the use of which would constitute a breach of the aforesaid injunction.
- (4) An order for appropriate measures for the dissemination and publication of the judgment and order to be taken at the expense of the Defendants.
- (5) An inquiry as to damages or, at the Claimants' election, an account of profits in respect of each and every act of infringement of the Patents.
- (6) An order that the Defendants pay the Claimants all sums found due together with interest pursuant to section 35A of the Senior Courts Act 1981 or pursuant to the Court's equitable jurisdiction for such period and at such rate as the Court sees fit.
- (7) Costs, together with interest on costs.

Further or other relief.

Claim No.	
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Does, or will, your claim include any issues under the Human Rights Act 1998? ☐ Yes ☒ No

Particulars of Claim attached

--

Statement of Truth

I understand that proceedings for contempt of court may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief in its truth.

☐ **I believe** that the facts stated in this Claim Form are true.

☒ **The Claimants believe** that the facts stated in this Claim Form are true. **I am authorised** by the Claimants to sign this statement.

Signature



☐ Claimant

☐ Litigation friend (where Judgment Creditor is a child or a Protected Party)

☒ Claimant's legal representative (as defined by CPR 2.3(1))

Date

Day

12

Month

07

Year

2021

Full name

NIGEL MARTIN STOATE

Name of applicant's legal representative's firm

TAYLOR WESSING LLP

If signing on behalf of firm or company give position or office held

PARTNER

Claimants' address to which documents should be sent.

Building and street

5 New Street Square

Second line of address

Town or city

London

County (optional)

Postcode

E	C	4	A		3	T	W
---	---	---	---	--	---	---	---

If applicable

Phone number

0207 300 7000

Fax number

0207 300 7100

DX number

DX 41 London

Your Ref.

Email

AbbottLibre@taylorwessing.com

EXHIBIT 5

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
WACO DIVISION**

DEXCOM, INC.,

Plaintiff,

V.

ABBOTT DIABETES CARE, INC.,
ABBOTT DIABETES CARE SALES CORP.

Defendants.

Civil Action No. 6:21-cv-00690-ADA

DEFENDANTS' SEALED OPPOSED MOTION TO TRANSFER

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DexCom already licensed the activities it's now accusing of infringement in this action. Any dispute about that license requires this action to be resolved in the District of Delaware, the venue mandated by the forum selection clause ("FSC") in the parties' existing license agreement. The Defendants Abbott Diabetes Care Inc. ("ADC Inc.") and Abbott Diabetes Care Sales Corp. ("Sales Corp.") therefore respectfully move under 28 U.S.C. § 1404(a) to transfer this action to that District, or if for some reason the FSC does not control, to the Northern District of California, which is clearly more convenient than the Western District of Texas.

I. INTRODUCTION

DexCom never should have filed its infringement complaint against FreeStyle Libre at all, much less in this District. Seven years ago, the parties ended their nearly decade-long patent disputes with a 2014 Settlement and License Agreement ("SLA"). Under that peace agreement—but for which ADC Inc. never would have dropped its Delaware infringement suits against DexCom—DexCom granted ADC Inc. a worldwide license. Every patent claim DexCom is asserting here falls within the scope of its license. DexCom also agreed to resolve any disputes relating to the SLA "exclusive[ly]" in Delaware courts. DexCom violated these agreements by bringing its infringement claims, and by doing so outside the District of Delaware.

The Supreme Court and Federal Circuit precedent require that the FSC "be given controlling weight" and the agreed upon Delaware court must decide the parties' dispute, so long as there is a "non-frivolous" argument that the license applies. *Atl. Marine Const. Co. v. U.S. Dist. Court for W. Dist. of Texas.*, 571 U.S. 49, 51, 63 (2013) (hereinafter "*AMC*"); *Gen Protecht Grp. v. Leviton Mfg. Co.*, 651 F.3d 1355, 1359 (Fed. Cir. 2011) (hereinafter "*GPG*"). DexCom's present action is an attempt to sidestep its agreement by suing Defendants here instead of Delaware and alleging infringement of licensed patent claims. No "extraordinary" public policy trumps DexCom's agreement. It must be enforced and this case must be transferred to Delaware.

Even if the FSC were improperly and unlawfully ignored as DexCom has done, this case would still be in the wrong place. The public and private interest factors demonstrate that this case would otherwise clearly belong in the Northern District of California, where the Defendants are both headquartered and the bulk of the evidence and witnesses resides.

In sum, the FSC is a unique circumstance that controls this case and requires transfer to Delaware. But even if the Court were to reach a different conclusion, then Fifth and Federal Circuit precedent would compel transfer to the Northern District of California.

II. THE SLA, ITS FSC, AND DEXCOM'S INFRINGEMENT CLAIMS

ADC Inc. and DexCom entered into the SLA on July 2, 2014 to resolve three patent lawsuits ADC Inc. brought against DexCom in the District of Delaware. Ex. A at 1, 29. That was after all seven ADC Inc. patents survived DexCom's serial attempts to cancel the patents through multiple reexaminations. *See* Ex. B, *Abbott Diabetes Care, Inc. v. DexCom, Inc.*, No. 1:05-cv-000590-GMS (D. Del.), Dkt. 78 at 1. As part of the SLA, ADC Inc. agreed to dismiss its infringement claims, and DexCom was "pleased" that the SLA allowed DexCom to avoid further litigation. *See* Ex. C (DexCom, Inc. Q2 2014 Earnings Call (Aug. 6, 2014)).

In the SLA, DexCom granted ADC Inc. a license "under DexCom Licensed Patents" for "ADC Products." ("**License Grant**"). Ex. A at 10 (¶ C.2). That license covers every DexCom patent claim directed to the subject matter of certain DexCom pre-2005 patents and applications. "DexCom Licensed Patents" is defined to include, *inter alia*, three categories (*id.* at 5-6 (¶ A.13):

1. **Subsection (a).** "All worldwide patents and patent applications ... that have an *actual filing date before January 1, 2005*, excluding those patents and patent applications identified on Exhibit A." ("**Pre-2005 Patents And Applications**").
2. **Subsection (b).** "All worldwide patents ... [that] *claim, priority* (in whole or in part) to any of the" Pre-2005 Patents And Applications.
3. **Subsection (c).** Patent claims that meet the following two conditions: **(1)** they are in patents that "claim[] priority to a patent [] captured in subsection (b), but [do] not claim[]

priority to a patent or application captured in Subsection (a)” (“**Claiming Criteria**”); and

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Ex. A at 21 (¶ H.3). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] As discussed below, that is precisely what

DexCom did for the claims it’s now asserting.

The SLA also contains a FSC, which states:

The United States Federal District Court for the District of Delaware shall have *exclusive jurisdiction over any dispute arising from or under or relating to this Agreement*, to the extent permitted by law.

Ex. A at 23 ¶ J.4. Moreover, each party stipulated to “personal jurisdiction and venue” in Delaware, waived “any” personal jurisdiction and venue defenses and “the right to seek transfer out of

¹ Emphasis is added throughout unless otherwise noted.

Delaware,” and agreed the Delaware court should apply Delaware law “without regard to ... conflict of laws principles.” *Id.* at 23, 26 (¶¶ J.4, K.7). These stipulations make sense because DexCom and ADC Inc. are both Delaware corporations. Dkt. 19, First Amended Complaint (“Am. Compl.”), ¶¶ 1, 3-4.

DexCom now asserts five patents against Defendants for “making, using, selling, and/or offering for sale” FreeStyle Libre continuous glucose monitoring systems (“CGMs”), specifically the FreeStyle Libre 14 day, the FreeStyle Libre 2, and the FreeStyle Libre 3 (collectively “**FreeStyle Libre Products**”). Am. Compl., ¶ 34. For each patent, DexCom identifies one claim that allegedly is infringed: Claim 1 of 11,000,213 (“213 Patent”), Claim 19 of 10,980,452 (“452 Patent”), Claim 19 of 10,702,215 (“215 Patent”), Claim 1 of 10,702,193 (“193 Patent”), and Claim 1 of 10,993,642 (“642 Patent”). *Id.*, ¶¶ 37, 46, 58, 71, 87 (collectively “**Asserted Patent Claims**”).

III. LEGAL STANDARDS

In this District, Fifth Circuit law generally applies to § 1404 motions, *In re Genentech, Inc.*, 566 F.3d 1338, 1341-42 (Fed. Cir. 2009), but Federal Circuit law applies to procedural matters in areas within its exclusive jurisdiction. *GPG*, 651 F.3d at 1359.

A FSC may be enforced through a motion to transfer under 28 U.S.C. § 1404(a). *AMC*, 571 U.S. at 58. The threshold inquiry for a § 1404(a) transfer is whether “the claim could have been filed” in “the judicial district to which transfer is sought.” *In re Volkswagen AG*, 371 F.3d 201, 203 (5th Cir. 2004). A valid FSC “represents [an] agreement as to the most proper forum” and “[should be] given controlling weight in all but the most exceptional cases.” *AMC*, 571 U.S. at 51.

A “forum-selection clause is prima facie valid.” *Powertech Tech. v. Tessera*, 660 F.3d 1301, 1310 (Fed. Cir. 2011). Where a FSC exists, the Court considers whether or not a defense or claim crosses the threshold required to trigger its application. *GPG*, 651 F.3d at 1359. Patent infringement claims trigger FSCs in patent license agreements where (1) the FSC “is not limited

to license related issues,” and (2) the defendant argues a license defense to infringement. *GPG*, 651 F.3d at 1359. ***The asserted license defense need only be “non-frivolous.”*** See *Uniloc USA, Inc. v. Cisco Sys., Inc.*, C.A. No. 15-1175, 2017 WL 959856, at *2 (E.D. Tex. Mar. 13, 2017). Defendants need only “come forward with colorable, factually specific arguments,” i.e. “more than a ‘bare allegation’ that it is entitled to a license defense.” *Id.* at *4. Arguments disputing a license’s existence should not be resolved. “If this Court were to ... resolv[e] which party has the prevailing argument ... then it would exceed its authority at this preliminary stage.” *Id.*

A valid FSC impacts the § 1404 analysis in two ways: (1) the plaintiff’s forum choice receives no weight, and (2) the court should not consider the parties’ private interests. *AMC*, 571 U.S. at 62-63. The court may consider only the § 1404 public interest factors (to the extent even applicable). These are: (1) the administrative difficulties flowing from court congestion; (2) the local interest in having localized interests decided at home; (3) the familiarity of the forum with the law that will govern the case; and (4) the avoidance of unnecessary problems of conflict of laws or in the application of foreign law. *Volkswagen AG*, 371 F.3d at 203.

If the FSC does not control, but the action could have been brought in another venue, courts then must weigh the relative convenience of the transferee and original districts. *Id.* Courts do so by weighing the public interest factors as well as four private interest factors: “(1) the relative ease of access to sources of proof; (2) the availability of compulsory process to secure the attendance of witnesses; (3) the cost of attendance for willing witnesses; and (4) all other practical problems that make trial of a case easy, expeditious and inexpensive.” *In re Volkswagen of Am.*, 545 F.3d 304, 312, 315 (5th Cir. 2008). The Federal Circuit has repeatedly held “that in a case featuring most witnesses and evidence closer to the transferee venue with few or no convenience factors favoring” the original venue the “court ***should grant*** a motion to transfer.” *E.g., In re Nintendo*,

589 F.3d 1194, 1198 (Fed. Cir. 2009); *In re Vistaprint*, 628 F.3d 1342, 1346 (Fed. Cir. 2010).

IV. ARGUMENT

Based on the SLA’s mandatory FSC, the District of Delaware should have “exclusive jurisdiction” over this case. If this Court finds that the FSC does not control, this case should be transferred to the Northern District of California based on the private and public interest factors.

A. Delaware and N.D. Cal. Are “Proper” Venues for the Case

There can be no dispute venue is proper in Delaware, where DexCom admits the Defendants are incorporated, or in the Northern District of California, where DexCom admits the Defendants have their “principal place[s] of business.” Am. Compl. ¶¶ 2-3. This threshold requirement for transfer under § 1404(a) is met under any theory.

B. The SLA’s FSC Requires Transfer To Delaware

As set out below, the FSC “is not limited to license related issues,” so it “necessarily covers disputes concerning patent issues.” *GPG*, 651 F.3d at 1359. And “[t]his case presents a non-frivolous dispute regarding the [license’s] scope.” *Id.* “Thus, there is no question in this case that the dispute ‘relates to or arises out of’” the SLA. *Id.* “The forum selection clause therefore applies.” *Id.* No “exceptional” circumstances necessary to override that clause exist. *AMC*, 571 U.S. at 63.

1. The FSC Is “Not Limited To License Related Issues”

The FSC is “not limited to license related issues such as the amount of royalty due, term of agreement, and cross licensing.” *GPG*, 651 F.3d at 1359. In fact, the FSC is at least as broad as the clause that the Federal Circuit found to “apply” to patent infringement claims in *GPG*. The SLA states, “the District of Delaware shall have *exclusive jurisdiction over any dispute arising from or under or relating to this Agreement*, to the extent permitted by law.” Ex. A at ¶ J.4. This mirrors the FSC language in *GPG* stating “[a]ny dispute between the Parties *relating to or arising out of this [Settlement Agreement] shall be prosecuted exclusively* in ... the District of New

Mexico.” *GPG*, 651 F.3d at 1358. This factor supports transfer.

2. Defendants Have A Non-Frivolous License Defense

Defendants’ defense surpasses the “non-frivolous” threshold. Nothing more is required.

a. ADC Inc.’s License Rights Capture All Asserted Patent Claims

[REDACTED] U.S. Prov. No. 60/614,764 (“764 Prov.”) (Ex. D), WO 2005/010518 (“518 Pub.”) (Ex. E), WO 2005/057168 (“168 Pub.”) (Ex. F), and/or U.S. Prov. No. 60/614,683 (“683 Prov.”) (Ex. G). Each was filed in 2004 and none is listed on Exhibit A of the 2014 SLA. Ex. A at 30. The arguments set forth below and in Defendants’ accompanying claim charts are exemplary and provided for the purpose of showing their defense is non-frivolous. While there are additional grounds supporting Defendants’ license defense, this is not the “time” for a “full resolution of the licensing defense issues.” *Implicit LLC v. Imperva, Inc.*, 19-CV-00040, 2020 WL 10356908, at *6 (E.D. Tex. Apr. 22, 2020) (quoting *Uniloc*, 2017 WL 959856, at *4). Should DexCom “oppose [Defendants’] reading of the Agreement and present [its] own interpretation,” “resolving the parties’ dispute will necessarily require the Court to interpret the Agreement—an exercise the [FSC] explicitly reserves for courts in [Delaware]. As a result, it would be improper to proceed any further on the merits of this case.” *EVS Codec Techs., LLC v. LG Elecs., Inc.*, No. 2:18-CV-00343-JRG, 2019 WL 2904747, at *4 (E.D. Tex. July 5, 2019); *Rovi Guides, Inc. v. Comcast Corp.*, No. 16-CV-00321, 2016 WL 6217201, at *4 (E.D. Tex. Oct. 25, 2016).

[REDACTED] The 764 Prov.’s specification includes in an appendix— which “forms part of the underlying provisional application,” *King Controls v. Winegard*, No. 2012-008614, 2012 WL 5983003, at *7 n. 9 (P.T.A.B. Nov. 27, 2012)—six prior art patents, three of which were assigned to TheraSense

(now ADC Inc.). Ex. D at D-1, D-38, D-150, D-158, D-221. According to DexCom, the “novel innovation” of the 213 Patent “allows” “factory calibration” of a glucose sensor. Am. Compl., ¶ 30. But factory calibration was already disclosed in the prior art TheraSense/ADC Inc. patents that DexCom incorporated into its 764 Prov. For instance, prior art U.S. Pat. No. 6,565,509 (“ADC 509 Patent”), which is part of the 764 Prov. specification, teaches:

Calibration data may be obtained in a variety of ways. For instance, the **calibration data may simply be factory-determined calibration measurements** which can be input into the on-skin sensor control unit ... using the receiver ... or may alternatively be stored in a calibration data storage unit

Ex. D at D-212 (U.S. Pat. No. 6,565,509 (“ADC 509 Patent”) at 43:35-41); *see also id.* at D-222 (ADC 690 Patent at 44:24-29), D-132 (U.S. Pat. No. 6,424,847 at 18:10-17), Ex. H (element 1(c)). Indeed, as established in the exemplary claim chart provided, the ADC 509 Patent discloses **all** of Claim 1’s elements, meaning Claim 1 is the “epitome” of obvious over the ADC 509 Patent. Ex. H. *Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1373 (Fed. Cir. 2019) (“[I]t is well settled that ‘a disclosure that anticipates under § 102 also renders the claim invalid under § 103, for ‘anticipation is the epitome of obviousness.’”)

[REDACTED]

[REDACTED] The 764 Prov. (incorporating the ADC 509 Patent) discloses all the elements of Claim 1. Ex. I. DexCom might argue that the 764 Prov. does not disclose a “code” on the product packaging to convey information for calibrating the sensor. To the contrary, the 764 Prov. discloses such a code in the same way the 642 Patent does. The 642 Patent describes “a calibration code” stored in the memory of a “readable chip” located, for example, on the “sensor packaging,” and used “during calibration of the sensor.” Ex. J at 73:49-74:26, 74:47-49. Similarly, the 764 Prov. discloses “calibration data unique to the particular sensor” stored in a “memory chip” that may be “placed on a shipping package or carton” and used “to accurately and reliably determine the

glucose sensor data.” Ex. I. at 8-12 (elements 1(c)-(d)). This disclosure is in prior art U.S. 5,497,772 (“772 Patent”) Ex. K, which the 764 Prov. incorporates by reference.

Moreover, using a code on the sensor packaging to convey calibration information would have been obvious to a person of ordinary skill in the art (“POSITA”) even without looking at the 772 Patent. In the glucose monitoring field, such codes had been used for decades on the packaging for test strips used with glucose monitors, which were precursors to sensors for glucose monitors. For example, describing the background knowledge in the field, U.S. 6,168,957 (“957 Patent”) explains how and why such codes were used for glucose test strips:

[I]t is necessary to assign to each lot of strips a calibration code that corrects for ... variability [among strips in a manufacturing batch]. ***The calibration code may be marked on the strip container***, and the user must enter the code into the meter when he or she begins to use a new batch of strips.

Ex. L at 1:52-60. It would have been obvious to a POSITA to use calibration codes on the packaging for a glucose sensor in the same way and for the same reasons that calibration codes had been used on the packaging for glucose test strips. [REDACTED]

_____ which incorporates the prior art 772 Patent (disclosing a memory chip with calibration information on the sensor packaging), alone or in combination with the prior art 957 Patent (disclosing a calibration code on the packaging for a glucose test strip), or a POSITA's general knowledge.

as set forth in the provided claim chart. Ex. M.

Ex. N.

[REDACTED]

The 683 Prov. discloses all of Claim 19's elements, as set forth in the provided claim chart. Ex. O.

[REDACTED]

Accordingly, the License Grant captures Claim 1 of the 642 Patent and Claim 19 of the 452 Patent. Those patents satisfy the Claiming Criteria.² [REDACTED]

[REDACTED]³

b. The Accused Activities Are Protected By DexCom's License

The accused FreeStyle Libre Products are also licensed "ADC Products." DexCom itself describes the accused products as "glucose monitoring system[s]" that "Abbott Diabetes Care, Inc. ... manufactures" and include "a transcutaneous electrochemical glucose sensor" that "uses a glucose oxidase enzyme to oxidize glucose and transfer electrons to a metal electrode," "a processor programmed to calibrate sensor data," and "a processor configured to evaluate sensor data." Am. Compl., ¶¶ 6, 39-41, 63-64, 89-91. [REDACTED]

[REDACTED] Taub Decl., ¶¶ 5-9. That fits the definition of "ADC Products" to include "electrochemical sensors, made by or for ADC, using an enzymatic reaction and using an osmium mediator to transfer electrons to an electroactive surface

² [REDACTED]

[REDACTED] For example, the 642 Patent claims priority to 7,905,833 (Ex. J at 1-2 (item 63)), which claims priority to the 764 Prov. and 683 Prov. Ex. Q at 1 (item 60)). Similarly, the 452 Patent claims priority to 8,615,282 (Ex. P at 1-2 (item 63)), which claims priority to the 764 Prov. and 683 Prov. Ex. R at 1 (item 60)).

³ The 213 Patent, 215 Patent, and 193 Patent are excluded from the definition of DexCom Licensed Patents because (1) the filing dates are after January 1, 2005 (Subsection (a)), (2) they do not claim priority to a patent or application with a filing date before January 1, 2005 (Subsection (b)), and (3) they do not claim priority to a patent that claims priority to a patent or application with a filing date before January 1, 2005 (Subsection (c)). Ex. A at 5-6 (¶ A.13).

Ex. A at 2-3 (¶ A.3).

Moreover, ADC Inc. is indisputably a party to the license, and

Bergschneider Decl. ¶ 3. “Accordingly, any subsequent sales are protected by the doctrine of patent exhaustion.” *Canon v. Tesser*, 146 F. Supp. 3d 568, 572, 580 (S.D.N.Y. 2015). As such, Defendants’ license defense covers the entire case—every asserted claim of every asserted patent and all accused products.

Even if the license defense were only relevant to ADC Inc., the Court should still transfer the case in its entirety. DexCom “cannot avoid application of the clause by making some allegations of conduct by a non-signatory [Sales Corp.] ... who has an ‘intertwined’ relationship with [ADC Inc.],” or “by suing an affiliate or affiliates of the party to the contract in which the clause appears.” *E.g., Brady v. RSM McGladrey, Inc.*, C.A. No. M-10-198, 2011 WL 13250551, *2 (S.D. Tex. Mar. 8, 2011); *Hurford Glob. LLC v. Rom Techs., Inc.*, C.A. No. 20-cv-484-JPG, 2020 WL 6487514, *6 (S.D. Ill. Nov. 4, 2020) (quoting *Am. Patriot Ins. Agency, Inc. v. Mut. Risk Mgmt., Ltd.*, 364 F.3d 884, 889 (7th Cir. 2004)). Also, severance “would create a significant risk of conflicting rulings” because “the same patents [would be] asserted against each Defendant in two different forums, which would require this Court and the District of Delaware to construe the exact same claim limitations” and both “Courts would likely address the same infringement issues.” *Implicit, LLC*, 2020 WL 10356908, at *7; *In re Rolls Royce*, 775 F.3d 671, 679, 681 (5th Cir. 2014) (granting writ of mandamus).

The parties’ FSC controls and this case should be transferred to Delaware.

C. If The FSC Does Not Apply, N.D. Cal. Is Clearly More Convenient

1. The Private Interest Factors Overwhelmingly Favor N.D. Cal.

a. Cost of Attendance For Willing Witnesses

Witness convenience “is probably the single most important factor in transfer analysis.” *Affinity Labs of Tex., LLC v. Blackberry Ltd.*, No. 13-CV-362, 2014 WL 10748106, at *4 (W.D. Tex. June 11, 2014). When the distance between an existing venue and a proposed venue “is more than 100 miles,” this factor “increases in direct relationship to the additional distance to be traveled.” *Id.* (citations omitted). It strongly favors transfer here.

Both Defendants have their principal places of business in Alameda, in N.D. Cal. Am. Compl., ¶¶ 3-4. Defendants’ Alameda headquarters is less than 10 miles from the Oakland Division of N.D. Cal., and **150 times closer** (~1485 miles) than Waco, Texas. Cary Decl. ¶¶ 3-4. There are even multiple public transit routes that connect Alameda and Oakland, while a flight from the San Francisco airport to Waco requires a full day of travel with a layover in Dallas. Cary Decl. ¶¶ 3-4. [REDACTED] Gellatly Decl. ¶ 3. [REDACTED]

[REDACTED] Gellatly Decl. ¶¶ 4-5. [REDACTED]

[REDACTED] *Id.* Moreover, DexCom has its principal place of business in San Diego, CA (~450 miles away) which is **3 times closer** than Waco, Texas (~1350 miles). Am. Compl., ¶ 1. DexCom has no known physical presence in Texas, let alone this District.

b. Relative Ease Of Access To Sources Of Proof

The ease of access to sources of proof is the second “most important transfer factor” and also favors transfer. *See Polaris Innovations Ltd. v. Dell Inc.*, No. 16-CV-451, 2016 WL 7077069, at *11 (W.D. Tex. Dec. 5, 2016). “The Federal Circuit has observed that in patent infringement cases, the bulk of the relevant evidence usually comes from the accused infringer, and therefore the location of the defendant’s documents tends to be the more convenient venue.” *DataQuill, Ltd.*

v. Apple Inc., No. A-13-CA-706-SS, 2014 WL 2722201, at *3 (W.D. Tex. June 13, 2014) (quotations omitted). The Court looks to “where the allegedly infringing products were researched, designed, developed and tested.” *XY, LLC v. Trans Ova Genetics, LC*, No. W-16-CA-00447-RP, 2017 WL 5505340, at *13 (W.D. Tex. Apr. 5, 2017). “Presumably, the bulk of the discovery material relating to a corporate party is located at the corporate headquarters,” *ACQIS LLC v. EMC Corp.*, 67 F. Supp. 3d 769, 775 (E.D. Tex. 2014).

This case is no exception. [REDACTED]

[REDACTED] See Taub Decl., ¶ 3. [REDACTED]

[REDACTED] Taub Decl., ¶ 4. [REDACTED]

[REDACTED] Taub Decl. ¶ 4.

c. Availability Of Compulsory Process

Many important nonparty witnesses, including those who will likely testify about Defendants’ products and the asserted patents, are based in, or much closer to, N.D. Cal. For example, many former ADC employees in or near N.D. Cal. personally contributed in material respect to the research and development of ADC’s accused technology as evidenced by their patented contributions, including, for example, Samuel Curry, Manuel Donnay, Daniel H. Lee, Andrew Naegeli, John Mazza, Duane Yamasaki, and Phillip Yee. See Cary Dec. ¶¶ 6-12. Most of the inventors of DexCom’s asserted patents are located in S.D. Cal. See Cary Dec. ¶¶ 13-24. Hauling these witnesses to WDTX would be highly inconvenient and, in any event, ***could not be compelled*** through judicial process.

The Austin facility that a third-party uses to manufacture aspects of an accused product

does not tip the balance. (This is the same “Research Boulevard” Flextronics facility that DexCom incorrectly claims is Defendants’ “place[.]” Am. Compl. ¶ 6.) Even if it has “some information relevant to [DexCom’s] infringement claims, the Court must also acknowledge that ‘the bulk of relevant evidence usually comes from the accused infringer.’” *Chrimar Sys., Inc. v. Juniper Networks, Inc.*, No. 6:15-CV-618, 2016 WL 126936, at *3 (E.D. Tex. Jan. 11, 2016); *see In re Apple Inc.*, 979 F.3d 1332, 1339-1340 (Fed. Cir. 2020) (finding the mere fact that “Flextronics, the third-party manufacturer of an Accused Product, may have relevant documents” did not “neutral[ize]” “the wealth of important information in NDCA”).

DexCom’s Amended Complaint alleges that Adam Heller, the co-founder of a company that became part of Abbott Diabetes Care, is a professor emeritus in Austin. *See* Am. Compl., ¶ 8. Dr. Heller has sworn that he is willing to travel to N.D. Cal. or Delaware for trial, and therefore his proximity to this Court should be given no weight. *See* Heller Decl. at ¶¶ 4-6.

“[I]n a case featuring most witnesses and evidence closer to the transferee venue with few or no convenience factors favoring the venue chosen by the plaintiff, the court should grant a motion to transfer.” *Nintendo*, 589 F.3d at 1198. That is this case.

D. The Public Interest Factors Support Transfer To Either Delaware or N.D. Cal.

The “**administrative difficulties flowing from court congestion**” factor is neutral for both Delaware and N.D. Cal. Although this District’s 19.1 month median time to trial is faster than Delaware’s 28.7 month median, Delaware has hundreds of fewer cases per judge, with an average of only 489 cases compared to this District’s average of 889 cases. Cary Decl. at ¶ 2. As for N.D. Cal., that district’s average of 745 cases per judge and 22.0 month median time to trial are better or “remarkably similar” to this District’s, making the “administrative difficulties” factor “neutral” for N.D. Cal. too. Cary Decl. at ¶ 2; *see In re Hulu, LLC*, No. 2021-142, 2021 WL 3278194, at *5 (Fed. Cir. Aug. 2, 2021) (finding trial time differences of 1.2 months and 4.7 months “remarkably

similar”); *SITO Mobile R&D IP v. Hulu, LLC*, No. 6-20-CV-00472-ADA, 2021 WL 1166772, at *8 (W.D. Tex. Mar. 24, 2021), *vacated sub nom. In re Hulu*.

The “**local interest in having localized interests decided at home**” factor favors transfer to Delaware because all parties are Delaware corporations, and strongly favors transfer to N.D. California because both Defendants have their principal place of business there and [REDACTED]

[REDACTED] “These are significant factors that give the Northern District of California a legitimate interest in adjudicating th[is] case[] ‘at home.’” *In re Samsung Elecs. Co.*, No. 2021-139, 2021 WL 2672136, at *7 (Fed. Cir. June 30, 2021). In contrast, Defendants’ contacts with this forum are minimal, and DexCom has no known presence at all in this District aside from the same sales activities it performs nationally. *In re Hoffmann–La Roche*, 587 F.3d 1333, 1338 (Fed. Cir. 2009). The remaining factors—“**familiarity of the forum with the law that will govern the case**” and “**avoidance of unnecessary problems of conflicts of laws**”—are neutral for N.D. Cal. because this case is governed by federal patent law, *In re TS Tech. USA Corp.*, 551 F.3d 1315, 1319-21 (Fed. Cir. 2008), and favor transfer to Delaware because the prior disputes were litigated in Delaware, the SLA is governed by Delaware law, and any disputes as to the scope or interpretation of the SLA must be determined under Delaware law. *See* Ex. A at 26 (¶ K.7). Federal judges in Delaware and the Third Circuit have greater familiarity with Delaware law governing this contract.

On balance, the public factors favor transfer, and certainly do not present the kind of “exceptional” circumstances that would otherwise outweigh the FSC. *AMC*, 571 U.S. at 63.

V. CONCLUSION

For the reasons stated, this case should be transferred to Delaware, as mandated by the parties’ SLA, or to the Northern District of California, which is clearly more convenient than this District.

Dated: September 20, 2021

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CERTIFICATE OF CONFERENCE

I hereby certify that on September 20, 2021, Abbott Defendants' counsel conferred in good faith with opposing counsel pursuant to Local Civil Rule 7(g), and DexCom is opposed to the relief sought. Accordingly, this Motion and the relief requested herein are submitted to the court for resolution.

/s/ J. Stephen Ravel

J. Stephen Ravel

CERTIFICATE OF SERVICE

I hereby certify that all counsel of record are being served with a copy of the foregoing document via electronic mail on September 20, 2021.

/s/ J. Stephen Ravel

J. Stephen Ravel

EXHIBIT 6

EXHIBIT H

Exhibit H

Claim Chart for U.S. Patent No. 11,000,213

Asserted Patent:

- U.S. Pat. No. 11,000,213 (“213 Patent”) (Ex. W)
 - Filing date: October 21, 2020
 - Earliest claimed priority date: March 10, 2005

Patent or Patent Application Captured in Subsection (a) of Paragraph A.13:

- U.S. Prov. No. 60/614,764 (“764 Provisional”) (Ex. D)
 - Filing date: September 30, 2004

Including references submitted in an appendix as part of the 764 Provisional (and incorporated by reference)¹:

- U.S. Pat. No. 6,565,509 (“ADC 509 Patent”)
 - Issue date: May 20, 2003
- U.S. Pat. No. 6,424,847 (“Mastrototaro 847 Patent”)
 - Issue date: July 23, 2002
- U.S. Application No. 10/648849 (“849 Application”)
 - Filing date: August 22, 2003

¹ The disclosure of a provisional application includes any materials submitted in an appendix. *See King Controls v. Winegard Co.*, 2012 WL 5983003, at *10 (P.T.A.B. Nov. 27, 2012) (an “appendage . . . forms part of the underlying provisional application”); *Ex Parte Cho*, 2015 WL 5118408, at *2 (P.T.A.B. Aug. 24, 2015) (the disclosure of a provisional includes “appendi[ces]” attached to the application and “any other portion of the originally-filed specification”). Also, “[w]hen a document is ‘incorporated by reference’ into a host document, such as a patent, the referenced document becomes effectively part of the host document as if it were explicitly contained therein.” *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1329 (Fed. Cir. 2001). The 764 Provisional states that “[a]ll references cited herein, including but not limited to published and unpublished applications, patents, and literature references, and also including but not limited to the references listed in the Appendix, are incorporated herein by reference in their entirety and are hereby made a part of this specification.” (764 Provisional at D-036 (¶ 0141).)

Exhibit H

Claim Chart for U.S. Patent No. 11,000,213

Claim 1	Exemplary Disclosure
<p>[1Pre] A glucose monitoring system comprising:</p>	<p>To the extent the preamble is limiting, the 764 Provisional discloses this subject matter. The 764 Provisional states that it “relates to systems and methods for <i>processing sensor data from a transcutaneous analyte sensor</i>.” (764 Provisional at D-004 (¶ 0001).) The 764 Provisional further discloses that “[i]n some embodiments, the analyte for measurement by the sensing regions, devices, and methods is <i>glucose</i>.” (<i>Id.</i> at D-010 (¶ 0046).)²</p> <p>The 764 Provisional also states that, “[i]n another alternative embodiment, the continuous glucose sensor comprises an intravascular sensor such as described with reference to U.S. Patent 6,424,847 to Mastrototaro et al.” (764 Provisional at D-016 (¶ 0065).) The Mastrototaro 847 Patent is both incorporated by reference (<i>id.</i> at D-036 (¶ 0141)) and included in the appendix of the 764 Provisional (<i>id.</i> at D-038). The Mastrototaro 847 Patent in turn “relates to <i>glucose monitor systems</i>.” (<i>Id.</i> at D-124 (Mastrototaro 847 Patent at 1:13).)</p> <p>The 764 Provisional also states that, “[i]n one alternative embodiment, the continuous glucose sensor comprises a transcutaneous sensor such as described in U.S. Patent 6,565,509 to Say et. al.” (764 Provisional at D-016 (¶ 0065).) The ADC 509 Patent is both incorporated by reference (<i>id.</i> at D-036 (¶ 0141)) and included in the appendix of the 764 Provisional (<i>id.</i> at D-038). The ADC 509 Patent in turn discloses that the transcutaneous sensor can be “[a] <i>glucose monitoring system</i>.” (<i>Id.</i> at D-219 (ADC 509 Patent at Claim 26).)</p> <p>Therefore, the 764 Provisional discloses a glucose monitoring system.</p>
<p>[1a] a transcutaneous electrochemical glucose sensor comprising: an in vivo portion configured to be inserted into a body of a host; and an ex vivo</p>	<p>The 764 Provisional discloses this subject matter. The 764 Provisional explains that its “transcutaneous analyte sensor system 10 of one embodiment,” where the analyte may be “glucose,” includes a “mounting unit 14 adapted for mounting on the skin of a host [and] a <i>sensor 32 adapted for transdermal insertion through the skin of a host</i>.” (764 Provisional at D-016–17 (¶¶ 0066–67).)</p>

² Emphasis added throughout unless otherwise noted.

Exhibit H

Claim Chart for U.S. Patent No. 11,000,213

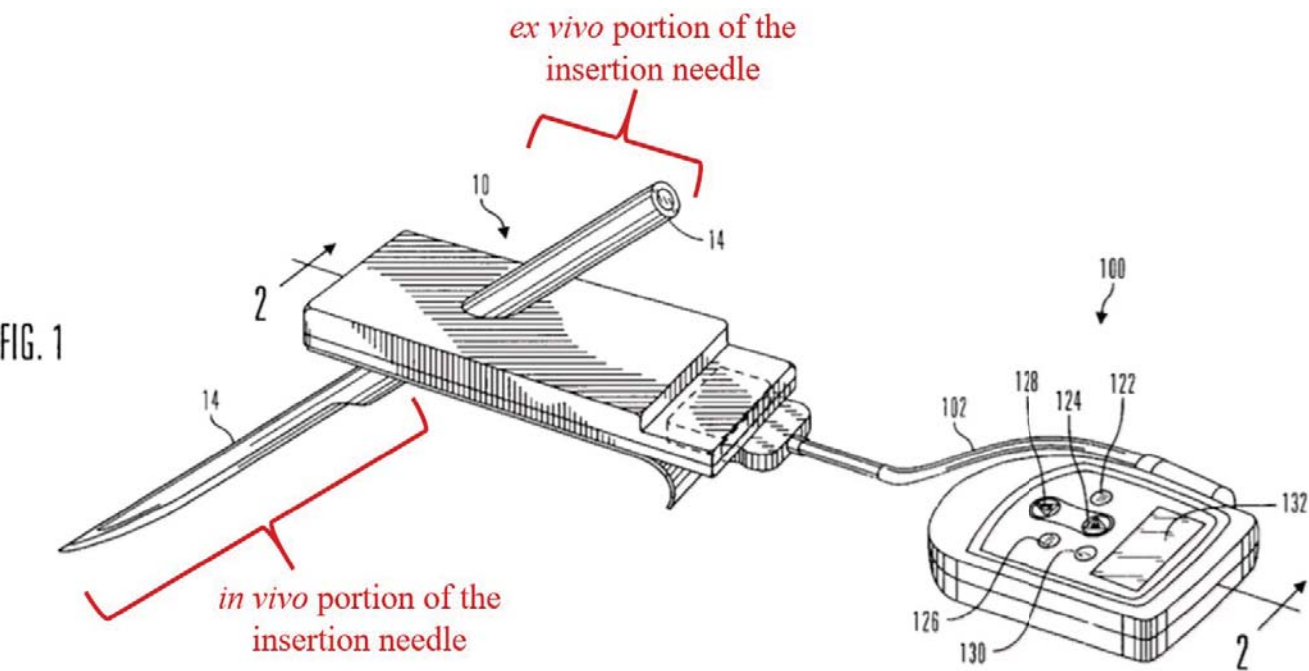
Claim 1	Exemplary Disclosure
<p>portion configured to remain outside of the body of the host; and</p>	<p>The Mastrototaro 847 Patent, appended to and incorporated by reference into the 764 Provisional, in turn discloses a “glucose sensor 12” that “<i>extends from the glucose sensor set 10 into the user’s body with electrodes 20 of the glucose sensor 12 terminating in the user’s subcutaneous tissue.</i>” (764 Provisional at D-126 (Mastrototaro 847 Patent at 5:51–58).) As shown in Fig. 1 of the Mastrototaro 847 Patent, using an insertion needle 14, for example, an <i>in vivo</i> portion is inserted through the skin into the host. (See <i>e.g., id.</i> at D-114 (Mastrototaro 847 Patent at Fig. 1).) The <i>ex vivo</i> portion remains outside the host where, for example, it can be connected to the sensor electronics. (See <i>e.g., id.</i>)</p>  <p>(764 Provisional at D-114 (Mastrototaro 847 Patent at Fig. 1) (annotated).)</p> <p>As discussed with respect to element 1Pre, the ADC 509 Patent, appended to and incorporated by reference into the 764 Provisional, discloses a “glucose monitoring system.” In addition, the ADC 509</p>

Exhibit H

Claim Chart for U.S. Patent No. 11,000,213

Claim 1	Exemplary Disclosure
	<p>Patent further teaches that its “glucose monitoring system” comprises “a <i>transcutaneous electrochemical glucose sensor</i>.” (764 Provisional at D-219 (ADC 509 Patent at Claim 26).) The ADC 509 Patent also explains that a “<i>portion</i>” of the “sensor 42” is “<i>configured for implantation (e.g., subcutaneous, venous, or arterial implantation) into a patient</i>,” and a sensor control unit 44. The sensor 42 is coupled to the sensor control unit 44 which is typically attached to the skin of a patient.” (<i>Id.</i> at D-193–94 (ADC 509 Patent at 6:62–7:1).)</p> <p>Therefore, the 764 Provisional, alone and through appending and incorporating by reference the ADC 509 Patent and the Mastrototaro 847 Patent, discloses a transcutaneous glucose sensor (<i>i.e.</i>, “a transcutaneous electrochemical glucose sensor” and a “glucose sensor 12” that “extends from the glucose sensor set 10 into the user’s body with electrodes 20 of the glucose sensor 12 terminating in the user’s subcutaneous tissue”) comprising an <i>in vivo</i> portion configured to be inserted into a body of a host (<i>i.e.</i>, “glucose sensor 12 terminating in the user’s subcutaneous tissue” and a “portion” of “sensor 42” that is “configured for implantation (e.g., subcutaneous, venous, or arterial implantation) into a patient”) and an <i>ex vivo</i> portion configured to remain outside of the body of the host (<i>i.e.</i>, a “portion” of “sensor 42” is “configured for implantation” into the body of the host and therefore a portion also remains outside the body of the host).</p>
<p>[1b] a processor programmed to calibrate sensor data based at least in part on prior calibration information generated before insertion of the transcutaneous electrochemical glucose sensor in the host, wherein the sensor data is associated with a</p>	<p>The 764 Provisional discloses this subject matter. As discussed further below, the ADC 509 Patent and the Mastrototaro 847 Patent, both appended to and incorporated by reference into the 764 Provisional, disclose transcutaneous electrochemical glucose sensors programmed to calibrated sensor data based at least in part on prior calibration information generated before insertion of the sensor in the host, wherein the sensor data is associated with a glucose concentration of a host. <i>See infra.</i></p> <p>Further, as explained below, a POSITA would have understood calibration information to comprise <i>sensitivity information</i> associated with the sensor. In this regard, the 213 Patent acknowledges that “typical” calibration methods “determine the <i>sensitivity</i> of the sensor...by analyzing sensor data from measurements taken by the sensor of a controlled solution.” (213 Patent at 17:66–18:8). According to the 213 Patent, the “<i>sensitivity</i>” of a sensor can be understood as “sensor signal strength with respect to analyte concentration.” (213 Patent at 77:23–25.) That “sensitivity” is used in a mathematical equation</p>

Exhibit H

Claim Chart for U.S. Patent No. 11,000,213

Claim 1	Exemplary Disclosure
<p>glucose concentration of the host, wherein the prior calibration information comprises prior sensitivity information associated with the transcutaneous electrochemical glucose sensor, and</p>	<p>called a “conversion function” that converts sensor signal into an estimated glucose concentration. (<i>See, e.g., id.</i> at 17:58–65, 78:24–32, 82:38–54, Fig. 22A.)</p> <p>The 764 Provisional discloses that calibration information can include sensitivity information. (<i>See, e.g.,</i> 764 Provisional at D-023–24 (¶¶ 0092–93), D-044 (¶ 0329), D-46 (¶ 0332), D-075 (¶ 0317), D-085 (Fig. 6).) For example, U.S. Application No. 10/648849 (“849 Application”) is included in an appendix as part of the 764 Provisional and also incorporated by reference. (764 Provisional at D-035–36 (¶¶ 0140-0141), D-038.) As part of the 784 Provisional, the 849 Application describes “sensitivity” and its use in the “conversion function” for calibration just as these concepts are described in the 213 Patent. (<i>Compare, e.g., id.</i> at D-043 (¶ 0323 (“sensitivity (e.g., sensor signal strength with respect to analyte concentration”)), D-075 (¶ 0317), D-085 (Fig. 6) <i>with</i> 213 Patent at 17:58–65, 77:23–25 (“sensitivity (e.g., sensor signal strength with respect to analyte concentration”)), 78:24–32, 82:38–54, Fig. 22A.)</p> <p>Further, as discussed with respect to element 1a, the Mastrototaro 847 Patent, appended to and incorporated by reference into the 764 Provisional, discloses a transcutaneous glucose sensor (<i>i.e.,</i> a “glucose sensor 12” that “extends from the glucose sensor set 10 into the user’s body with electrodes 20 of the glucose sensor 12 terminating in the user’s subcutaneous tissue.”) The Mastrototaro 847 Patent further teaches that a “glucose monitor 100 measures a continuous electrical current signal (ISIG) generated by the glucose sensor 12 relative to a concentration of glucose present in the subcutaneous tissue of the user’s body.” (764 Provisional at D-127 (Mastrototaro 847 Patent at 8:38–42).) The Mastrototaro 847 Patent also discloses that “<i>glucose sensors 12 are calibrated during the manufacturing process.</i>” (<i>Id.</i> at D-132 (Mastrototaro 847 Patent at 18:10–11).) To calibrate the sensors, “<i>sensors from the same manufacturing lot, that have similar properties, are calibrated using a sampling of glucose sensors 12 from the population and a solution with a known glucose concentration.</i>” (<i>Id.</i> at D-132 (Mastrototaro 847 Patent at 18:11–15).) Through this process, a “<i>sensitivity ratio</i>” is determined for the lot of sensors and “is provided with the glucose sensor 12 and is entered into the glucose monitor 100 or the post processor 200 by the user or another individual.” (<i>Id.</i> at D-132 (Mastrototaro 847 Patent at 18:15–18).) “The glucose monitor 100 takes raw glucose sensor data from the glucose sensor 12 and assesses it during real-time and/or stores it for later processing or downloading to the data processor 200 . . . <i>[and to] calibrate the data.</i>” (<i>Id.</i> at D-132 (Mastrototaro 847 Patent at 6:27–37).)</p>

Exhibit H

Claim Chart for U.S. Patent No. 11,000,213

Claim 1	Exemplary Disclosure
	<p>Therefore, the 764 Provisional, at least by appending and incorporating by reference the Mastrototaro 847 Patent, discloses a processor (<i>i.e.</i>, “post processor 200”) programmed to calibrate sensor data based at least in part on calibration information generated before insertion of the transcutaneous glucose sensor in the host (<i>i.e.</i>, “glucose sensors 12 are calibrated during the manufacturing process” and entered into processor 200 which “calibrate[s] the [sensor] data” “from the glucose sensor 12”), wherein the sensor data is associated with a glucose concentration of the host (<i>i.e.</i>, “a continuous electrical current signal (ISIG) generated by the glucose sensor 12 relative to a concentration of glucose present in the subcutaneous tissue of the user’s body”), wherein the prior calibration information comprises prior sensitivity information associated with the transcutaneous electrochemical glucose sensor (<i>i.e.</i>, a “sensitivity ratio” generated by “using a sampling of glucose sensors 12 from the population and a solution with a known glucose concentration” “during the manufacturing process”).</p> <p>Further, the ADC 509 Patent, appended to and incorporated by reference into the 764 Provisional, in turn discloses that “calibration data may be used by the processing circuit 109 <i>to correct signals from the sensor 42.</i>” (764 Provisional at D-212 (ADC 509 Patent at 43:25–44).) These signals “can be correlated to an amount, concentration, or level of an analyte in the sample.” (<i>Id.</i> at D-193 (ADC 509 Patent at 5:59–60).) This analyte may be “glucose.” (<i>Id.</i> at D-193 (ADC 509 Patent at 5:35).) The ADC 509 Patent states that “<i>calibration data may simply be factory-determined calibration measurements</i> which can be input into the on-skin sensor control unit 44 using the receiver 99 or <i>may alternatively be stored in a calibration data storage unit 100</i> within the on-skin sensor control unit 44 itself.” (<i>Id.</i> at D-212 (ADC 509 Patent at 43:25–44).)</p> <p>Therefore, the 764 Provisional, at least by appending and incorporating by reference the ADC 509 Patent and the 849 Application, discloses a processor (<i>i.e.</i>, “processing circuit 109”) programmed to calibrate sensor data based at least in part on calibration information generated before insertion of the transcutaneous glucose sensor in the host (<i>i.e.</i>, utilizing “calibration data . . . to correct signals from the [transcutaneous electrochemical glucose] sensor 42” where the calibration data may be “factory-determined”), wherein the sensor data is associated with a glucose concentration of the host (<i>i.e.</i>, signals “can be correlated to an amount, concentration, or level of an analyte in the sample” where the analyte can be “glucose”), wherein the prior calibration information comprises prior sensitivity information</p>

Exhibit H

Claim Chart for U.S. Patent No. 11,000,213

Claim 1	Exemplary Disclosure
	associated with the transcutaneous electrochemical glucose sensor (<i>i.e.</i> , “factory-determined calibration measurements” including sensor sensitivity as described in the 764 Provisional).
<p>[1c] wherein the processor is programmed to calibrate the sensor data without a need for a reference analyte concentration measurement obtained after insertion of the <i>in vivo</i> portion of the transcutaneous glucose sensor.</p>	<p>The 764 Provisional discloses this subject matter. As discussed above with respect to element 1b, the Mastrototaro 847 Patent, appended to and incorporated by reference into the 764 Provisional, discloses a processor (<i>i.e.</i>, “post processor 200”) programmed to calibrate sensor data (<i>i.e.</i>, processor 200 “calibrate[s] the [sensor] data” “from the glucose sensor 12”). The Mastrototaro 847 Patent also teaches that its “glucose sensors 12 are calibrated during the manufacturing process,” which is prior to insertion of the <i>in vivo</i> portion in a patient or host. (764 Provisional at D-132 (Mastrototaro 847 Patent at 18:10–18).)</p> <p>Therefore, the 764 Provisional, at least by appending and incorporating by reference the Mastrototaro 847 Patent, discloses that the processor (<i>i.e.</i>, “post processor 200”) programmed to calibrate sensor data (<i>i.e.</i>, processor 200 “calibrate[s] the [sensor] data” “from the glucose sensor 12”) without a need for a reference analyte concentration measurement obtained after insertion of the <i>in vivo</i> portion of the transcutaneous glucose sensor (<i>i.e.</i>, “glucose sensors 12 are calibrated during the manufacturing process”).</p> <p>Further, as discussed above with respect to element 1b, the ADC 509 Patent, appended to and incorporated by reference into the 764 Provisional, discloses a processor (<i>i.e.</i>, “processing circuit 109”) programmed to calibrate sensor data (<i>i.e.</i>, utilizing “calibration data . . . to correct signals from the [transcutaneous electrochemical glucose] sensor 42”). The ADC 509 Patent further discloses that, “calibration data may simply be factory-determined calibration measurements,” which are measurements taken in a factory prior to insertion of the <i>in vivo</i> portion of the transcutaneous glucose sensor in a patient or host. (764 Provisional at D-212 (ADC 509 Patent at 43:25–44).)</p> <p>Therefore, the 764 Provisional, at least by appending and incorporating by reference the ADC 509 Patent, discloses that the processor is programmed to calibrate sensor data (<i>i.e.</i>, “processing circuit 109”) programmed to calibrate sensor data (<i>i.e.</i>, utilizing “calibration data . . . to correct signals from the [transcutaneous electrochemical glucose] sensor 42”) without a need for a reference analyte</p>

Exhibit H

Claim Chart for U.S. Patent No. 11,000,213

Claim 1	Exemplary Disclosure
	concentration measurement obtained after insertion of the in vivo portion of the transcutaneous glucose sensor (<i>i.e.</i> , “calibration data may simply be factory-determined calibration measurements”).

EXHIBIT 7

EXHIBIT I

Exhibit I

Claim Chart for U.S. Patent No. 10,993,642

Asserted Patent:

- U.S. Pat. No. 10,993,642 (“642 Patent”) (Ex. J)
 - Filing date: November 3, 2020
 - Earliest claimed priority date: March 10, 2005

Patent or Patent Application Captured in Subsection (a) of Paragraph A.13:

- U.S. Prov. No. 60/614,764 (“764 Provisional”) (Ex. D)
 - Filing date: September 30, 2004

Including references submitted in an appendix as part of the 764 Provisional (and incorporated by reference)¹:

- U.S. Pat. No. 6,565,509 (“ADC 509 Patent”)
 - Issue date: May 20, 2003
- U.S. Pat. No. 6,424,847 (“Mastrototaro 847 Patent”)
 - Issue date: July 23, 2002
- U.S. Application No. 10/648849 (“849 Application”)
 - Filing date: August 22, 2003

Including other references incorporated by reference as part of the 764 Provisional² (*see* 764 Provisional at D-036 (¶ 0141)):

- U.S. Pat. No. 5,497,772 (“772 Patent”) (Ex. K)
 - Issue date: March 12, 1996
- U.S. Pat. No. 6,400,974 (“974 Patent”) (Ex. X)
 - Issue date: June 4, 2002

Additional References:

- U.S. Pat. No. 6,168,957 (“957 Patent”) (Ex. L)
 - Issue date: January 2, 2001

¹ The specification of a provisional application includes any materials submitted in an appendix. *See King Controls v. Winegard Co.*, 2012 WL 5983003, at *10 (P.T.A.B. Nov. 27, 2012) (an “appendage . . . forms part of the underlying provisional application”); *Ex Parte Cho*, 2015 WL 5118408, at *2 (P.T.A.B. Aug. 24, 2015) (the disclosure of a provisional includes “appendi[ces]” attached to the application and “any other portion of the originally-filed specification”).

² The 764 Provisional states: “[a]ll references cited herein, including but not limited to published and unpublished applications, patents, and literature references, and also including but not limited to the references listed in the Appendix, are incorporated herein by reference in their entirety and are hereby made a part of this specification.” (764 Provisional at p. D-036 (¶ 0141).) “When a document is ‘incorporated by reference’ into a host document, such as a patent, the referenced document becomes effectively part of the host document as if it were explicitly contained therein.” *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1329 (Fed. Cir. 2001).

Exhibit I

Claim Chart for U.S. Patent No. 10,993,642

Claim 1	Exemplary Disclosure
<p>[1Pre] A glucose monitoring system comprising:</p>	<p>To the extent the preamble is limiting, the 764 Provisional discloses this subject matter. The 764 Provisional states that it “relates to systems and methods for <i>processing sensor data from a transcutaneous analyte sensor</i>.” (764 Provisional at D-004 (¶ 0001).) The 764 Provisional further discloses that “[i]n some embodiments, the analyte for measurement by the sensing regions, devices, and methods is <i>glucose</i>.” (<i>Id.</i> at D-010 (¶ 0046).)³</p> <p>The 764 Provisional also states that, “[i]n another alternative embodiment, the continuous glucose sensor comprises an intravascular sensor such as described with reference to U.S. Patent 6,424,847 to Mastrototaro et al.” (764 Provisional at D-016 (¶ 0065).) The Mastrototaro 847 Patent is both incorporated by reference (<i>id.</i> at D-036 (¶ 0141)) and included in the appendix of the 764 Provisional (<i>id.</i> at D-038). The Mastrototaro 847 Patent in turn “relates to <i>glucose monitor systems</i>.” (<i>Id.</i> at D-124 (Mastrototaro 847 Patent at 1:13).)</p> <p>The 764 Provisional also states that, “[i]n one alternative embodiment, the continuous glucose sensor comprises a transcutaneous sensor such as described in U.S. Patent 6,565,509 to Say et. al.” (764 Provisional at D-016 (¶ 0065).) The ADC 509 Patent is both incorporated by reference (<i>id.</i> at D-036 (¶ 0141)) and included in the appendix of the 764 Provisional (<i>id.</i> at D-038). The ADC 509 Patent in turn discloses that the transcutaneous sensor can be “[a] <i>glucose monitoring system</i>.” (<i>Id.</i> at D-219 (ADC 509 Patent at Claim 26).)</p> <p>Therefore, the 764 Provisional discloses a glucose monitoring system.</p>
<p>[1a] a transcutaneous glucose sensor comprising: an in vivo portion configured to be inserted into a body of a host; and an ex</p>	<p>The 764 Provisional discloses this subject matter. The 764 Provisional explains that its “transcutaneous analyte sensor system 10 of one embodiment,” where the analyte may be “glucose,” includes a “mounting unit 14 adapted for mounting on the skin of a host [and] <i>a sensor 32 adapted for transdermal insertion through the skin of a host</i>.” (764 Provisional at D-016–17 (¶¶ 0066–67).)</p> <p>The Mastrototaro 847 Patent, appended to and incorporated by reference into the 764 Provisional, in turn discloses a “glucose sensor 12” that “<i>extends from the glucose sensor set 10 into the user’s body</i> with electrodes 20 of the glucose sensor 12 <i>terminating in the user’s subcutaneous tissue</i>.” (764 Provisional at D-</p>

³ Emphasis is added throughout unless otherwise noted.

Exhibit I

Claim Chart for U.S. Patent No. 10,993,642

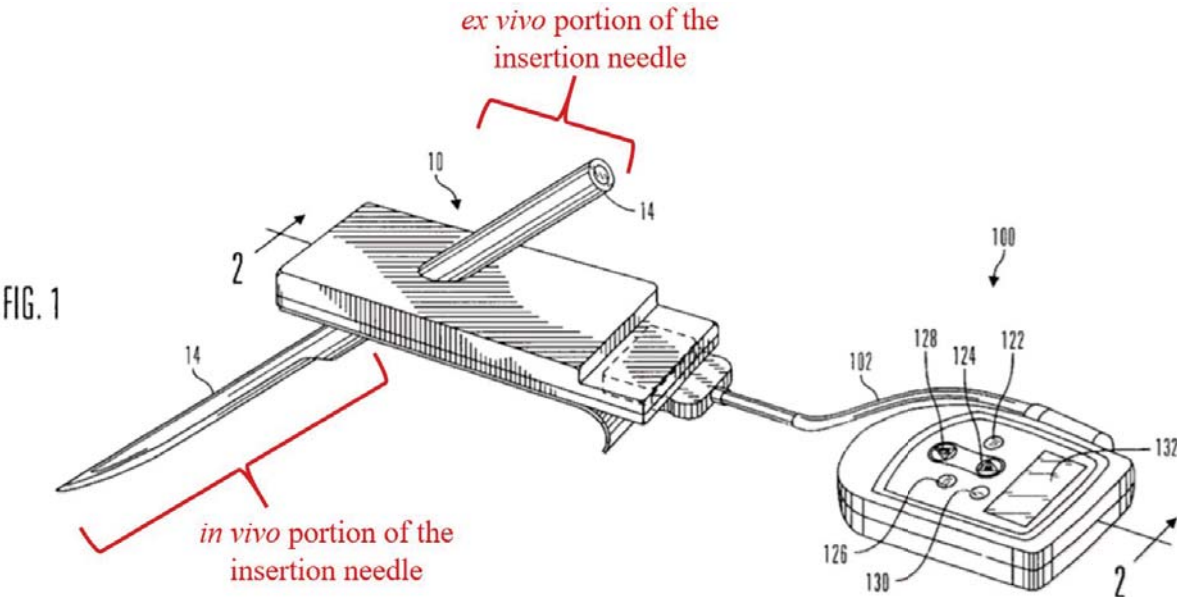
Claim 1	Exemplary Disclosure
<p>vivo portion configured to remain outside of the body of the host; and</p>	<p>126 (Mastrototaro 847 Patent at 5:51–58.) As shown in Fig. 1 of the Mastrototaro 847 Patent, using an insertion needle 14, for example, an <i>in vivo</i> portion is inserted through the skin into the host. (See <i>e.g.</i>, <i>id.</i> at D-114 (Mastrototaro 847 Patent at Fig. 1).) The <i>ex vivo</i> portion remains outside the host where, for example, it can be connected to the sensor electronics. (See <i>e.g.</i>, <i>id.</i>)</p>  <p>(764 Provisional at D-114 (Mastrototaro 847 Patent at Fig. 1) (annotated).)</p> <p>As discussed with respect to element 1Pre, the ADC 509 Patent, appended to and incorporated by reference into the 764 Provisional, discloses a “glucose monitoring system.” In addition, the ADC 509 Patent further teaches that its “glucose monitoring system” comprises “a <i>transcutaneous electrochemical glucose sensor</i>.” (764 Provisional at D-219 (ADC 509 Patent at Claim 26).) The ADC 509 Patent also explains that a “<i>portion</i>” of the “sensor 42” is “<i>configured for implantation (e.g., subcutaneous, venous, or arterial implantation) into a patient</i>,” and a sensor control unit 44. The sensor 42 is coupled to the sensor control unit 44 which is typically attached to the skin of a patient.” (<i>Id.</i> at D-193–94 (ADC 509 Patent at 6:62–7:1).)</p>

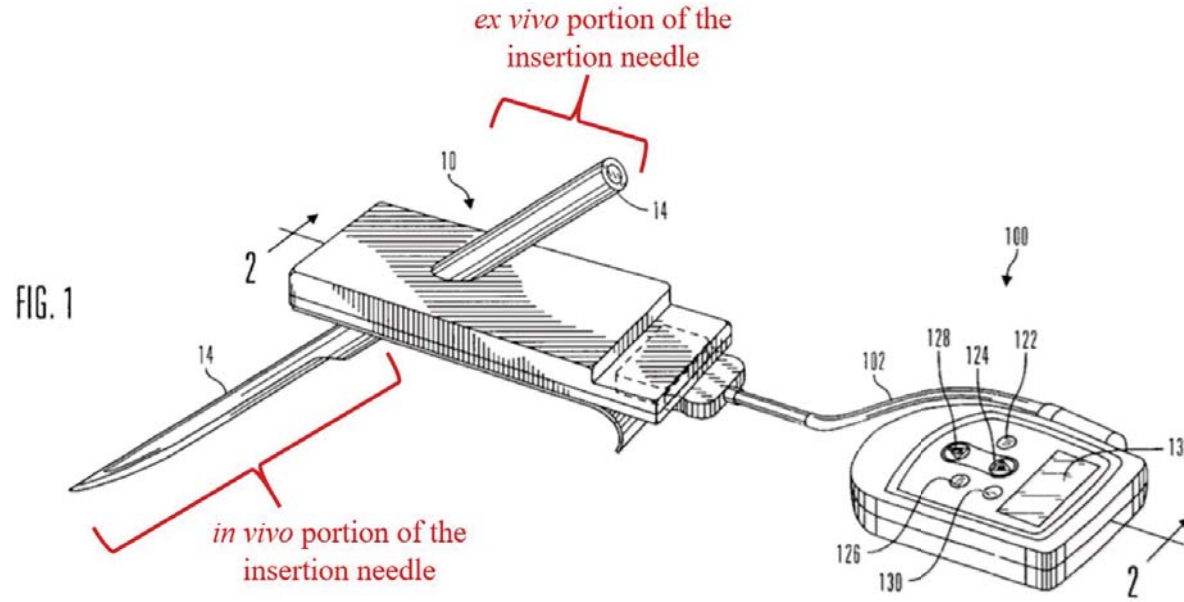
Exhibit I

Claim Chart for U.S. Patent No. 10,993,642

Claim 1	Exemplary Disclosure
	<p>Therefore, the 764 Provisional, alone and through appending and incorporating by reference the ADC 509 Patent and the Mastrototaro 847 Patent, discloses a transcutaneous glucose sensor (<i>i.e.</i>, “a transcutaneous electrochemical glucose sensor” and a “glucose sensor 12” that “extends from the glucose sensor set 10 into the user’s body with electrodes 20 of the glucose sensor 12 terminating in the user’s subcutaneous tissue”) comprising an <i>in vivo</i> portion configured to be inserted into a body of a host (<i>i.e.</i>, “glucose sensor 12 terminating in the user’s subcutaneous tissue” and a “portion” of “sensor 42” that is “configured for implantation (e.g., subcutaneous, venous, or arterial implantation) into a patient”) and an <i>ex vivo</i> portion configured to remain outside of the body of the host (<i>i.e.</i>, a “portion” of “sensor 42” is “configured for implantation” into the body of the host and therefore a portion also remains outside the body of the host). The 764 Provisional discloses this subject matter. The 764 Provisional explains that its “transcutaneous analyte sensor system 10 of one embodiment,” where the analyte may be “glucose,” includes a “mounting unit 14 adapted for mounting on the skin of a host [and] a sensor 32 adapted for transdermal insertion through the skin of a host.” (764 Provisional at D-016–17 (¶¶ 0066-67).)</p> <p>The Mastrototaro 847 Patent, appended to and incorporated by reference into the 764 Provisional, in turn discloses a “glucose sensor 12” that “<i>extends from the glucose sensor set 10 into the user’s body</i> with electrodes 20 of the glucose sensor 12 <i>terminating in the user’s subcutaneous tissue.</i>” (764 Provisional at D-126 (Mastrototaro 847 Patent at 5:51–58).) As shown in Fig. 1 of the Mastrototaro 847 Patent, using an insertion needle 14, for example, an <i>in vivo</i> portion is inserted through the skin into the host. (<i>See e.g., id.</i> at D-114 (Mastrototaro 847 Patent at Fig. 1).) The <i>ex vivo</i> portion remains outside the host where, for example, it can be connected to the sensor electronics. (<i>See e.g., id.</i>)</p>

Exhibit I

Claim Chart for U.S. Patent No. 10,993,642



(764 Provisional at D-114 (Mastrototaro 847 Patent at Fig. 1) (annotated).)

As discussed with respect to element 1Pre, the ADC 509 Patent, appended to and incorporated by reference into the 764 Provisional, discloses a “glucose monitoring system.” In addition, the ADC 509 Patent further teaches that its “glucose monitoring system” comprises “a *transcutaneous electrochemical glucose sensor*.” (764 Provisional at p. D-219 (ADC 509 Patent at Claim 26).) The ADC 509 Patent also explains that a “*portion*” of the “sensor 42” is “*configured for implantation (e.g., subcutaneous, venous, or arterial implantation) into a patient*,” and a sensor control unit 44. The sensor 42 is coupled to the sensor control unit 44 which is typically attached to the skin of a patient.” (*Id.* at D-193–194 (ADC 509 Patent at 6:62–7:1).)

Therefore, the 764 Provisional, alone and through appending and incorporating by reference the ADC 509 Patent and the Mastrototaro 847 Patent, discloses a transcutaneous glucose sensor (*i.e.*, “a transcutaneous electrochemical glucose sensor” and a “glucose sensor 12” that “extends from the glucose sensor set 10 into the user’s body with electrodes 20 of the glucose sensor 12 terminating in the user’s subcutaneous tissue”) comprising an *in vivo* portion configured to be inserted into a body of a host (*i.e.*, “glucose sensor 12 terminating in the user’s subcutaneous tissue” and a “portion” of “sensor 42” that is “configured for

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Claim 1	Exemplary Disclosure
	<p>implantation (e.g., subcutaneous, venous, or arterial implantation) into a patient”) and an <i>ex vivo</i> portion configured to remain outside of the body of the host (<i>i.e.</i>, a “portion” of “sensor 42” is “configured for implantation” into the body of the host and therefore a portion also remains outside the body of the host).</p>
<p>[1b] a processor programmed to calibrate sensor data based at least in part on prior calibration information generated before insertion of the transcutaneous glucose sensor in the host, wherein the sensor data is associated with a glucose concentration of the host, wherein the prior calibration information comprises prior sensitivity information associated with the transcutaneous glucose sensor,</p>	<p>The 764 Provisional discloses this subject matter. As discussed further below, the ADC 509 Patent and the Mastrototaro 847 Patent, both appended to and incorporated by reference into the 764 Provisional, disclose transcutaneous electrochemical glucose sensors programmed to calibrated sensor data based at least in part on prior calibration information generated before insertion of the sensor in the host, wherein the sensor data is associated with a glucose concentration of a host. <i>See infra</i>.</p> <p>Further, as explained below, a POSITA would have understood calibration information to comprise sensitivity information associated with the sensor. In this regard, the 642 Patent acknowledges that “a person of ordinary skill in the art” would understand “sensitivity” (or “slope”) to refer “to an amount of electrical current produced by a predetermined amount (unit) of the measured analyte” (e.g., glucose) and that sensitivity is a parameter that directly impacts sensor calibration. (642 Patent at 17:49–57, 18:37–49.) According to the 642 Patent, the “sensitivity” of a sensor can be understood as “sensor signal strength with respect to analyte concentration.” (642 Patent at 91:12–13.) That “sensitivity” is used in a mathematical equation called a “conversion function” that converts a sensor signal into an estimated glucose concentration. (<i>Id.</i> at 87:44–45, 89:50–65, 98:66–99:2; <i>see also id.</i> at 17:49–57, 22:7–15, 115:22–23, 117:31–32.)</p> <p>The 764 Provisional discloses that calibration information includes sensitivity information. (<i>See, e.g.</i>, 764 Provisional at pp. D-043 (¶ 0323 (“sensitivity (e.g., sensor signal strength with respect to analyte concentration))), D-075 (¶ 0317), D-085 (Fig. 6), D-129–30 (Mastrototaro 847 Patent at 12:24–14:51).) Indeed, the 764 Provisional describes “sensitivity” and its use in the “conversion function” for calibration just as these concepts are described in the 642 Patent. (<i>Compare, e.g., id.</i> at D-403 (¶ 0323 (“sensitivity (e.g., sensor signal strength with respect to analyte concentration))), D-075 (¶ 0317), D-085 (Fig. 6) <i>with</i> 642 Patent at 17:49–57, 18:37–49, 91:12–13 (“sensitivity (e.g., sensor signal strength with respect to analyte concentration))).</p>

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Claim 1	Exemplary Disclosure
	<p>As discussed with respect to element 1a, the Mastrototaro 847 Patent, appended to and incorporated by reference into the 764 Provisional, discloses a transcutaneous glucose sensor (<i>i.e.</i>, a “glucose sensor 12” that “extends from the glucose sensor set 10 into the user’s body with electrodes 20 of the glucose sensor 12 terminating in the user’s subcutaneous tissue.”) The Mastrototaro 847 Patent further teaches that a “glucose monitor 100 measures a continuous electrical current signal (ISIG) generated by the glucose sensor 12 relative to a concentration of glucose present in the subcutaneous tissue of the user’s body.” (764 Provisional at D-127 (Mastrototaro 847 Patent at 8:38–42).) The Mastrototaro 847 Patent also discloses that “glucose sensors 12 are calibrated during the manufacturing process.” (<i>Id.</i> at D-132 (Mastrototaro 847 Patent at 18:10–11).) To calibrate the sensors, “sensors from the same manufacturing lot, that have similar properties, are calibrated using a sampling of glucose sensors 12 from the population and a solution with a known glucose concentration.” (<i>Id.</i> at D-132 (Mastrototaro 847 Patent at 18:11–15).) Through this process, a “sensitivity ratio” is determined for the lot of sensors and “is provided with the glucose sensor 12 and is entered into the glucose monitor 100 or the post processor 200 by the user or another individual.” (<i>Id.</i> at D-132 (Mastrototaro 847 Patent at 18:15–18).) “The glucose monitor 100 takes raw glucose sensor data from the glucose sensor 12 and assesses it during real-time and/or stores it for later processing or downloading to the data processor 200 . . . [and to] calibrate the data.” (<i>Id.</i> at p. D-126 (Mastrototaro 847 Patent at 6:27–37).)</p> <p>Therefore, the 764 Provisional, at least by appending and incorporating by reference the Mastrototaro 847 Patent, discloses a processor (<i>i.e.</i>, “post processor 200”) programmed to calibrate sensor data based at least in part on calibration information generated before insertion of the transcutaneous glucose sensor in the host (<i>i.e.</i>, “glucose sensors 12 are calibrated during the manufacturing process” and entered into processor 200 which “calibrate[s] the [sensor] data” “from the glucose sensor 12”), wherein the sensor data is associated with a glucose concentration of the host (<i>i.e.</i>, “a continuous electrical current signal (ISIG) generated by the glucose sensor 12 relative to a concentration of glucose present in the subcutaneous tissue of the user’s body”), wherein the prior calibration information comprises prior sensitivity information associated with the transcutaneous electrochemical glucose sensor (<i>i.e.</i>, a “sensitivity ratio” generated by “using a sampling of glucose sensors 12 from the population and a solution with a known glucose concentration” “during the manufacturing process”).</p>

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Claim 1	Exemplary Disclosure
	<p>Further, the ADC 509 Patent, appended to and incorporated by reference into the 764 Provisional, in turn discloses that “calibration data may be used by the processing circuit 109 <i>to correct signals from the sensor 42.</i>” (764 Provisional at p. D-212 (ADC 509 Patent at 43:25–44).) These signals “can be correlated to an amount, concentration, or level of an analyte in the sample.” (<i>Id.</i> at D-193 (ADC 509 Patent at 5:59–60).) This analyte may be “glucose.” (<i>Id.</i> at D-193 (ADC 509 Patent at 5:35).) The ADC 509 Patent states that “<i>calibration data may simply be factory-determined calibration measurements</i> which can be input into the on-skin sensor control unit 44 using the receiver 99 or <i>may alternatively be stored in a calibration data storage unit 100</i> within the on-skin sensor control unit 44 itself.” (<i>Id.</i> at D-212 (ADC 509 Patent at 43:25–44).)</p> <p>Therefore, the 764 Provisional, at least by appending and incorporating by reference the ADC 509 Patent and the 849 Application, discloses a processor (<i>i.e.</i>, “processing circuit 109”) programmed to calibrate sensor data based at least in part on calibration information generated before insertion of the transcutaneous glucose sensor in the host (<i>i.e.</i>, utilizing “calibration data . . . to correct signals from the [transcutaneous electrochemical glucose] sensor 42” where the calibration data may be “factory-determined”), wherein the sensor data is associated with a glucose concentration of the host (<i>i.e.</i>, signals “can be correlated to an amount, concentration, or level of an analyte in the sample” where the analyte can be “glucose”), wherein the prior calibration information comprises prior sensitivity information associated with the transcutaneous electrochemical glucose sensor (<i>i.e.</i>, “factory-determined calibration measurements” including sensor sensitivity as described in the 764 Provisional).</p>
[1c] wherein the prior calibration information is associated with a sensor code,	<p>The 764 Provisional discloses this subject matter. The Mastrototaro 847 Patent, appended to and incorporated by reference into the 764 Provisional, discloses that “<i>glucose sensors 12 are calibrated during the manufacturing process</i>” and that a “<i>sensitivity ratio is provided with the glucose sensor 12 and is entered into the glucose monitor 100 or the post processor 200</i> by the user or another individual.” (764 Provisional at D-132 (Mastrototaro 847 Patent at 18:10–18).)</p> <p>Further, the ADC 509 Patent, appended to and incorporated by reference into the 764 Provisional, discloses that “<i>factory-determined calibration measurements</i>” that form “<i>the calibration data . . .</i> can be input into the on-skin sensor control unit 44 using the receiver 99 or <i>may alternatively be stored in a calibration data</i></p>

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Claim 1	Exemplary Disclosure
	<p><i>storage unit 100</i> within the on-skin sensor control unit 44 itself.” (764 Provisional at p. D-212 (ADC 509 Patent at 43:36–41).)</p> <p>Therefore, the 764 Provisional, at least through appending and incorporating by reference the ADC 509 Patent and the Mastrototaro 847 Patent, discloses that the prior calibration information (<i>i.e.</i>, “factory-determined calibration measurements” and “glucose sensors 12 are calibrated during the manufacturing process”) is associated with a sensor code (<i>i.e.</i> “the calibration data . . . stored in a calibration data storage unit 100” and a “sensitivity ratio . . . provided with the glucose sensor 12.”).</p> <p>Furthermore, U.S. App. No. 10/648,849 (“849 Application”), appended to and incorporated by reference into the 764 Provisional (764 Provisional at pp. D-035–36 (¶¶ 0140–141), D-038), teaches that data processing methods “can be employed in conjunction with any sensor or monitor measuring levels of an analyte in vivo, wherein the level of the analyte fluctuates over time, including . . . such sensors as described in U.S. Patent 6,400,974 to Lesho” (<i>id.</i> at D-077 (849 Application at ¶ 0320)). The 974 Patent in turn discloses that its “internal storage circuits can store ID codes and parametric values such as calibration constants.” (974 Patent at 5:26–27.)</p> <p>The 764 Provisional further incorporates by reference U.S. Pat. No. 5,497,772 to Schulman. (<i>See</i> 764 Provisional at D-062, D-103, D-146–48, D-151–53 (<i>e.g.</i>, 764 Provisional at p. D-153 (U.S. Pat. No. 6,512,939 at 9:64–67) (“The electronic operation of the monitoring system is preferably as is described in U.S. Pat. No. 5,497,772, Schulman, et al, incorporated herein, in its entirety, by reference.”)).) The 772 Patent in turn discloses that its “glucose monitoring system . . . includes a memory element having a calibration data stored therein unique to said glucose sensor.” (772 Patent at Claim 15.)</p> <p>As explained above, both the 974 Patent and the 772 Patent are specifically incorporated by reference in their entirety in the 764 Provisional. The 764 Provisional additionally discloses “converting sensor data into calibrated data using a conversion function.” (764 Provisional at p. D-005 (¶ 0005).) A person of ordinary skill in the art (“POSITA”) would have been motivated to combine the sensor code concepts of the 974 Patent and the 772 Patent with the related 764 Provisional disclosures. In order to calibrate data using a conversion function, the system of the 764 Provisional must incorporate calibration information specific to the sensor. Both the 974 Patent and the 772 Patent disclose a useful method of incorporating this calibration information</p>

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	<p>into the disclosed system by using codes associated with calibration information. Therefore to the extent not already disclosed, incorporating the codes of the 974 Patent and the 772 Patent into the system of the 764 Provisional results in an obvious variant of the system.</p> <p>To the extent this subject matter is not explicitly disclosed in the 764 Provisional, it was merely an obvious variant of the subject matter of the 764 Provisional as of the Effective Date of the ADC-Dexcom SLA (July 2, 2014) and the date the 642 Patent issued (May 4, 2021).</p> <p>Indeed, even prior to 2005, calibration information associated with codes was well known in the art. For example, U.S. Pat. No. 6,168,957 (“957 Patent”), describing the known background art, explains that glucose test strips (precursors to glucose sensors), “by their nature, do not lend themselves to large-scale manufacture with adequate strip-to-strip reproducibility from one batch to the next. Consequently, it is necessary to <i>assign to each lot of strips a calibration code that corrects for this variability</i>.” (957 Patent at 1:52–56.) The 957 Patent thus teaches prior calibration information (<i>i.e.</i>, “calibration . . . that corrects for this variability”) associated with a code (<i>i.e.</i>, “calibration code”).</p> <p>To the extent not already disclosed, adding the calibration code from the 957 Patent to the system described in the 764 Provisional would have resulted in an obvious variant. Both references disclose systems for calibrating glucose monitoring devices. A POSITA would readily have incorporated the calibration code from the 957 Patent into the calibration system of the 764 Provisional. In order to calibrate data using a conversion function, the system of the 764 Provisional incorporates calibration information specific to the sensor. The 957 Patent discloses a useful method of incorporating this calibration information into the disclosed system by using codes associated with calibration information.</p>
[1d] wherein the sensor code is located in or on a packaging holding the transcutaneous glucose sensor,	<p>The 764 Provisional discloses this subject matter.</p> <p>As discussed above with respect to element 1c, the 772 Patent, incorporated by reference into the 764 Provisional, discloses a sensor code (<i>i.e.</i> a “memory element having a calibration data stored therein unique to said glucose sensor”). The 772 Patent further discloses that its system has “a memory chip 48, housed in a round chip package . . . <i>[and] is placed on a shipping package or carton 50 wherein the sensor assembly 32</i></p>

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Claim 1	Exemplary Disclosure
	<p><i>is placed during shipping.</i>” (772 Patent at 6:17–33.) The 772 Patent further explains that “the memory chip 48 includes calibration data unique to the particular sensor assembly 32, which calibration data is used by monitor 34 as it processes the signals obtained from the sensor assembly 32 in order to accurately and reliably determine the glucose sensor data.” (<i>Id.</i> at 6:17–33.)</p> <div data-bbox="804 459 1560 1021" data-label="Image"> <p>The diagram shows a rectangular box representing a sensor packaging assembly, labeled '50' at the bottom. Inside the box, the word 'PACKAGE' is written in large, bold, capital letters. Attached to the top-left corner of the box is a small, dark, circular component labeled '48', which is a memory chip. A red arrow points from the text 'Chip storing calibration data located on the sensor packaging' to the chip 48.</p> </div> <p>(772 Patent at Fig. 1 (excerpted and annotated).)</p> <p>The 764 Provisional teaches “converting sensor data into calibrated data using a conversion function.” (764 Provisional at p. D-005 (¶ 0005).) The 764 Provisional also discloses that “[a]fter the usable life of the sensor,” the host “preferably sav[es] the electronics unit for reuse.” (<i>Id.</i> at D-035 (¶ 0139).) Furthermore, the sensor code is “unique for a batch of sensor systems.” (<i>Id.</i> at D-019 (¶ 0076).) As the electronics unit is reusable, it must be supplied with a new code for each new sensor. The 772 Patent discloses a useful method of providing this unique sensor code to the electronics unit by including it on the sensor packaging. The 764 Provisional similarly discloses using a “chip” with a “unique or near-unique signature that can be detected by the electronics unit . . . as the sensor code.” (<i>Id.</i> at D-020 (¶ 0077).) Therefore, a POSITA would have been</p>

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	<p>motivated to combine these related concepts. To the extent not already disclosed, incorporating the sensor code on the product packaging into the system of the 764 Provisional would have resulted in an obvious variant of the system.</p> <p>To the extent this subject matter is not explicitly disclosed in the 764 Provisional, it was merely an obvious variant of the subject matter of the 764 Provisional as of the Effective Date of the ADC-Dexcom SLA (July 2, 2014) and the date the 642 Patent issued (May 4, 2021).</p> <p>Indeed, even prior to 2005, locating calibration codes in or on packaging was well known in the art. For example, the 957 Patent, describing the known background art, explains that glucose test strips (precursors to glucose sensors) “by their nature, do not lend themselves to large-scale manufacture with adequate strip-to-strip reproducibility from one batch to the next. Consequently, it is necessary to <i>assign to each lot of strips a calibration code that corrects for this variability</i>.” (957 Patent at 1:52-56.) The 957 Patent further explains that “<i>the calibration code may be marked on the strip container</i>, and the user must enter the code into the meter when he or she begins to use a new batch of strips.” (<i>Id.</i> at 1:56-59.) The 957 Patent thus teaches a code (<i>i.e.</i>, “calibration code”) located in or on packaging (<i>i.e.</i>, “marked on the strip container”).</p> <p>Adding the calibration code on the packaging, as taught in the 957 Patent, for the system described in the 764 Provisional would have resulted in an obvious variant. Both references disclose systems for calibrating glucose monitoring devices. A POSITA would readily have implemented the calibration code on the packaging, as taught in the 957 Patent, for the calibration system of the 764 Provisional. In order to calibrate data using a conversion function, the system of the 764 Provisional incorporates calibration information specific to each sensor. The 957 Patent discloses a useful method of incorporating this calibration information into the disclosed system by using codes associated with calibration information and allowing for easy access of the codes on the packaging.</p>
[1e] wherein the processor is programmed to calibrate the sensor	<p>The 764 Provisional discloses this subject matter. As discussed above with respect to element 1b, the Mastrototaro 847 Patent, appended to and incorporated by reference into the 764 Provisional, discloses a processor (<i>i.e.</i>, “post processor 200”) programmed to calibrate sensor data (<i>i.e.</i>, processor 200 “<i>calibrate[s] the [sensor] data</i>” “from the glucose sensor 12”). The Mastrototaro 847 Patent also teaches that its “<i>glucose</i></p>

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Claim 1	Exemplary Disclosure
<p>data without a need for a reference analyte concentration measurement obtained after insertion of the <i>in vivo</i> portion of the transcutaneous glucose sensor.</p>	<p><i>sensors 12 are calibrated during the manufacturing process,”</i> which is prior to insertion of the <i>in vivo</i> portion in a patient or host. (764 Provisional at p. D-132 (Mastrototaro 847 Patent at 18:10–18).)</p> <p>Therefore, the 764 Provisional, at least by appending and incorporating by reference the Mastrototaro 847 Patent, discloses that the processor (<i>i.e.</i>, “post processor 200”) programmed to calibrate sensor data (<i>i.e.</i>, processor 200 “calibrate[s] the [sensor] data” “from the glucose sensor 12”) without a need for a reference analyte concentration measurement obtained after insertion of the <i>in vivo</i> portion of the transcutaneous glucose sensor (<i>i.e.</i>, “glucose sensors 12 are calibrated during the manufacturing process”).</p> <p>Further, as discussed above with respect to element 1b, the ADC 509 Patent, appended to and incorporated by reference into the 764 Provisional, discloses a processor (<i>i.e.</i>, “processing circuit 109”) programmed to calibrate sensor data (<i>i.e.</i>, utilizing “calibration data . . . to correct signals from the [transcutaneous electrochemical glucose] sensor 42”). The ADC 509 Patent further discloses that, “calibration data may simply be factory-determined calibration measurements,” which are measurements taken in a factory prior to insertion of the <i>in vivo</i> portion of the transcutaneous glucose sensor in a patient or host. (764 Provisional at p. D-212 (ADC 509 Patent at 43:25–44).)</p> <p>Therefore, the 764 Provisional, at least by appending and incorporating by reference the ADC 509 Patent, discloses that the processor is programmed to calibrate sensor data (<i>i.e.</i>, “processing circuit 109”) programmed to calibrate sensor data (<i>i.e.</i>, utilizing “calibration data . . . to correct signals from the [transcutaneous electrochemical glucose] sensor 42”) without a need for a reference analyte concentration measurement obtained after insertion of the <i>in vivo</i> portion of the transcutaneous glucose sensor (<i>i.e.</i>, “calibration data may simply be factory-determined calibration measurements”).</p>

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EXHIBIT M

Exhibit M

U.S. Patent No. 10,702,215

Asserted Patent:

- U.S. Pat. No. 10,702,215 (“215 Patent”) (Ex. Y)
 - Filing date: November 5, 2019
 - Earliest claimed priority date: October 30, 2012

Patent or Patent Application Captured in Subsection (a) of Paragraph A.13:

- U.S. Prov. No. 60/614,764 (“764 Provisional”) (Ex. D)
 - Filing date: September 30, 2004

Including references submitted as part of the 764 Provisional (and incorporated by reference)¹:

- U.S. Pat. No. 6,565,509 (“ADC 509 Patent”)
 - Issue date: May 20, 2003

Additional References

- U.S. Pub. No. 2003/0125612 (“612 Publication”) (Ex. Z)
 - Publication date: July 3, 2003
- Dexcom STS-User’s Guide (“STS User’s Guide”) (Ex. AA)
 - Publication date: 2006

¹ The specification of a provisional application includes any materials submitted in an appendix. *See King Controls v. Winegard Co.*, 2012 WL 5983003, at *10 (P.T.A.B. Nov. 27, 2012) (an “appendage . . . forms part of the underlying provisional application”); *Ex Parte Cho*, 2015 WL 5118408, at *2 (P.T.A.B. Aug. 24, 2015) (the disclosure of a provisional includes “appendi[ces]” attached to the application and “any other portion of the originally-filed specification”). Also, “[w]hen a document is ‘incorporated by reference’ into a host document, such as a patent, the referenced document becomes effectively part of the host document as if it were explicitly contained therein.” *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1329 (Fed. Cir. 2001). The 764 Provisional states: “[a]ll references cited herein, including but not limited to published and unpublished applications, patents, and literature references, and also including but not limited to the references listed in the Appendix, are incorporated herein by reference in their entirety and are hereby made a part of this specification.” (764 Provisional at p. D-036 (¶ 0141).)

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Claim 19	Exemplary Disclosure
<p>[19Pre] A system for processing data, the system comprising:</p>	<p>To the extent the preamble is limiting, the 764 Provisional discloses this subject matter. The 764 Provisional states that, “in one alternative embodiment, the continuous glucose sensor comprises a transcutaneous sensor such as described in U.S. Patent 6,565,509 to Say et. al.” (764 Provisional at D-016 (¶ 0065).) The ADC 509 Patent was included in the appendix of the 764 Provisional (<i>id.</i> at D-038) and is also incorporated by reference (<i>id.</i> at D-036 (¶ 0141)).</p> <p>The ADC 509 Patent discloses an “invention [that] relates to methods and devices for the continuous and/or automatic <i>in vivo</i> monitoring of the level of an analyte using a subcutaneously implantable sensor.” (764 Provisional at D-191 (ADC 509 Patent at 2:18–21).) The ADC 509 Patent further discloses embodiments that include “a sensor control unit” with “<i>a processing circuit</i>” that “at minimum, obtains signals from the sensor circuit . . . and/or measurement circuit . . . and provides the signals to an optional transmitter” (<i>Id.</i> at D-208 (ADC 509 Patent at 36:44–57).) The processing circuit may also “<i>partially or completely evaluate the signals from the sensor and convey the resulting data to the optional transmitter</i> . . . and/or activate an optional alarm system . . . if the analyte level exceeds a threshold.” (<i>Id.</i> (ADC 509 Patent at 36:57–62).)²</p> <p>Thus, the 764 Provisional, at least through appending and incorporating by reference the ADC 509 Patent, discloses a system for processing data.</p>
<p>[19a] a continuous analyte sensor configured to be implanted within a body; and</p>	<p>The 764 Provisional discloses this subject matter. The ADC 509 Patent, appended to and incorporated by reference into the 764 Provisional, asserts that “[t]here is a need for a small, comfortable device which can continuously monitor the level of an analyte, such as glucose, while still permitting the patient to engage in normal activities.” (764 Provisional at D-191 (ADC 509 Patent at 2:5–8).) The ADC 509 Patent therefore proposes an “invention [that] relates to methods and devices for the <i>continuous</i> and/or automatic <i>in vivo monitoring of the level of an analyte using a subcutaneously implantable sensor</i>.” (<i>Id.</i> (ADC 509 Patent at 2:18–21).) The ADC 509 Patent teachings are “applicable to <i>an analyte monitoring system using an implantable sensor for the in vivo determination of a concentration of an analyte</i>, such as glucose or lactate, in a fluid. <i>The sensor can</i></p>

² Emphasis added throughout unless otherwise noted.

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Claim 19	Exemplary Disclosure
	<p><i>be, for example, subcutaneously implanted in a patient for the continuous or periodic monitoring an analyte</i> [sic] in a patient's interstitial fluid. This can then be used to infer the glucose level in the patient's bloodstream.” (<i>Id.</i> at p. D-193 (ADC 509 Patent at 5:32–39).)³</p> <p>Thus, the 764 Provisional, at least through appending and incorporating by reference the ADC 509 Patent, discloses a continuous analyte sensor (<i>i.e.</i>, “sensor for the in vivo determination of a concentration of an analyte” through “continuous . . . monitoring”) configured to be implanted within a body (<i>i.e.</i>, “subcutaneously implanted in a patient”).</p>
<p>[19b] sensor electronics configured to receive and process sensor data output by the sensor, the sensor electronics including a processor configured to:</p>	<p>The 764 Provisional discloses this subject matter. The ADC 509 Patent, appended to and incorporated by reference into the 764 Provisional, discloses an “on-skin sensor control unit 44” that is connected to “sensor 42.” (764 Provisional at D-205 (ADC 509 Patent at 29:19–21).) “The on-skin sensor control unit 44 [] typically includes at least a portion of the <i>electronic components that operate the sensor 42 and the analyte monitoring device system 40</i>. One embodiment of the electronics in the on-skin control unit 44 is illustrated as a block diagram in FIG. 18A. The electronic components of the on-skin sensor control unit 44 typically include a power supply 95 for operating the on-skin control unit 44 and the sensor 42, a sensor circuit 97 for obtaining signals from and operating the sensor 42, a measurement circuit 96 that converts sensor signals to a desired format, and <i>a processing circuit 109 that, at minimum, obtains signals from the sensor circuit 97 and/or measurement circuit 96 and provides the signals to an optional transmitter 98. In some embodiments, the processing circuit 109 may also partially or completely evaluate the signals from the sensor 42</i> and convey the resulting data to the optional transmitter 98 and/or activate an optional alarm system 94 (see FIG. 18B) if the analyte level exceeds a threshold. <i>The processing circuit 109 often includes digital logic circuitry.</i>” (<i>Id.</i> at D-208 (ADC 509 Patent at 36:44–63).)</p>

³ Emphasis added throughout unless otherwise noted.

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Claim 19	Exemplary Disclosure
	<p style="text-align: center;">FIG. 18A</p> <p style="text-align: center;">(764 Provisional at p. D-175 (ADC 509 Patent at Fig. 18A) (annotated).)</p>

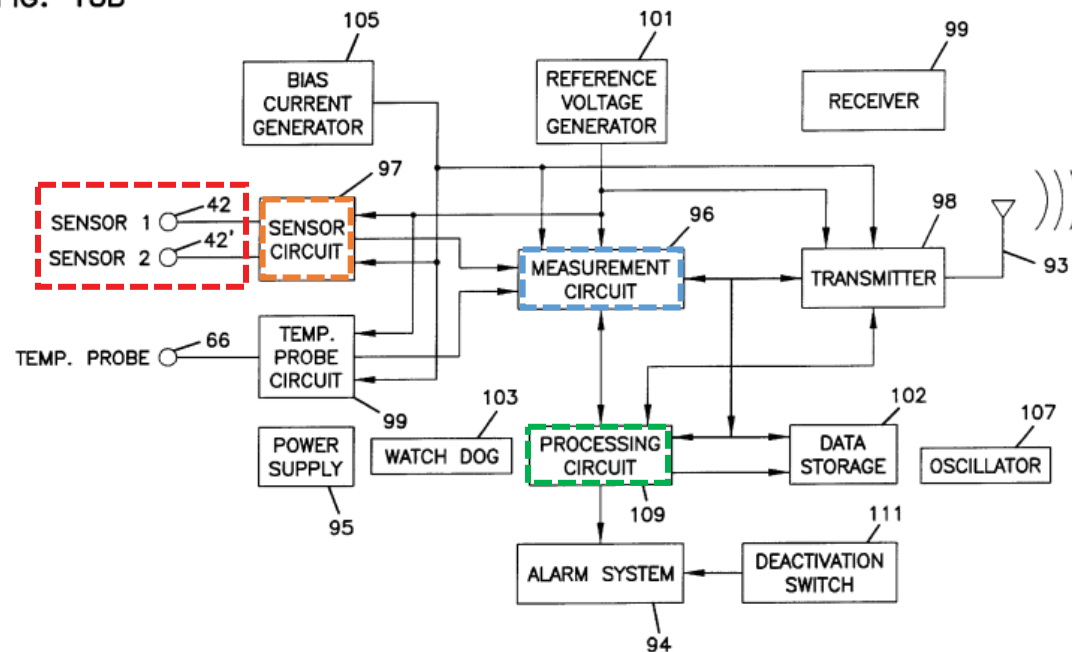
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Claim 19

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FIG. 18B



(764 Provisional at D-176 (ADC 509 Patent at Fig. 18B) (annotated).)

Thus, the 764 Provisional, at least through appending and incorporating by reference the ADC 509 Patent, discloses sensor electronics (*i.e.*, “electronic components that operate the sensor 42 [outlined in **red** above] and the analyte monitoring device system 40”) configured to receive and process sensor data output by the sensor (*i.e.*, “obtains signals from the sensor circuit 97 [outlined in **orange** above] and/or measurement circuit 96 [outlined in **blue** above]” and “may also partially or completely evaluate the signals from the sensor 42”), the sensor electronics including a processor (*i.e.*, “electronic components of the on-skin sensor control unit 44 typically include . . . a processing circuit 109 [outlined in **green** above]”).

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Claim 19	Exemplary Disclosure
<p>[19c] evaluate sensor data using a first function to determine whether a real time glucose value meets one or more user settable first criteria;</p>	<p>The 764 Provisional discloses this subject matter. The ADC 509 Patent, appended to and incorporated by reference into the 764 Provisional, discloses that on-skin sensor control unit may include an “alarm system 104 that, based on the data from the processing circuit 109, warns the patient of a potentially detrimental condition of the analyte.” (764 Provisional at D-213 (ADC 509 Patent at 45:8–11).) “The alarm system 104 is triggered when the data from the processing unit 109 reaches or equals a threshold value.” (<i>Id.</i> (ADC 509 Patent at 45:15–17).) “[T]hreshold values” may be “for blood glucose levels,” and “may correspond to interstitial fluid glucose concentrations or electrode measurements (e.g., current values or voltage values obtained by conversion of current measurements) that correlate to the above-mentioned blood glucose levels.” (<i>Id.</i> (ADC 509 Patent at 45:24–28).) “The analyte monitor device may be configured so that the threshold levels for these or any other conditions may be programmable by the patient and/or a medical professional.” (<i>Id.</i> (ADC 509 Patent at 45:28–31).)</p> <p>Thus, the 764 Provisional at least through appending and incorporating by reference the ADC 509 Patent, discloses evaluating sensor data (<i>i.e.</i>, “data from the processing circuit 109”) using a first function (<i>i.e.</i>, the “alarm system 104” function that compares “blood glucose levels” to “threshold values”) to determine whether a real time glucose value meets one or more user settable first criteria (<i>i.e.</i>, “threshold values” that “may be programmable by a patient and/or a medical professional”).</p>
<p>[19d] evaluate sensor data using a second function to determine whether a parameter indicative of a glucose value meets one or more non-user settable second criteria;</p>	<p>The 764 Provisional discloses this subject matter. As discussed with respect to element 19c above, the ADC 509 Patent, appended to and incorporated by reference into the 764 Provisional, discloses evaluating sensor data (<i>i.e.</i>, “data from the processing circuit 109”) using a first function (<i>i.e.</i>, “alarm system 104”) to determine whether a real time glucose value meets one or more user settable first criteria (<i>i.e.</i>, “threshold values” that “may be programmable by a patient and/or a medical professional”).</p> <p>In addition, the ADC 509 Patent further teaches that “[t]he alarm system 104 may also ... be activated when the rate of change or acceleration of the rate of change in analyte level increase or decrease reaches or exceeds a threshold rate or acceleration. For example, in the case of a subcutaneous glucose monitor, the alarm system might be activated if the rate of change in glucose concentration exceeds a threshold value which might indicate that a hyperglycemic or hypoglycemic condition is likely to</p>

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	<p>occur.” (764 Provisional at D-213 (ADC 509 Patent at 45:53–61).) The ADC 509 Patent also teaches that “[e]ach condition that can trigger an alarm may have a different alarm activation condition. In addition, the alarm activation condition may change depending on current conditions. (<i>Id.</i> (ADC 509 Patent at 46:3–6).) And, as discussed with respect to element 19c above, the ADC 509 Patent teaches that “[t]he analyte monitor device <i>may</i> be configured so that the threshold levels for these or any other conditions may be programmable by the patient and/or a medical professional.” (<i>Id.</i> (ADC 509 Patent at 45:28–31).) In other words, each given threshold may <i>or may not</i> be programmable (<i>i.e.</i>, user-settable).</p> <p>Thus, the 764 Provisional at least through appending and incorporating by reference the ADC 509 Patent, discloses evaluating sensor data (<i>i.e.</i>, “data from the processing circuit 109”) using a second function (<i>i.e.</i>, “alarm system 104” function that compares “rate of change in glucose concentration” to a “threshold value”) to determine whether a parameter indicative of a glucose value (<i>i.e.</i>, “rate of change in glucose concentration”) meets one or more non-user settable second criteria (<i>i.e.</i>, “threshold values” that “may”—or <i>may not</i>—“be programmable by a patient and/or a medical professional”).</p> <p>To the extent the claimed subject matter of this limitation is not disclosed in the 764 Provisional, it would merely have been an obvious variant of the subject matter of the 764 Provisional as of the Effective Date of the ADC-Dexcom SLA (July 2, 2014) and the date that the 215 Patent issued (July 7, 2020). Prior to 2005, evaluating glucose sensor data using both user-settable and non-user-settable criteria was well-known, and to the extent not already disclosed, adopting it for the transcutaneous glucose sensors of the 764 Provisional would have been obvious.</p> <p>As an example, US 2003/0125612 (“612 Publication”) discloses a glucose monitoring system with multiple alarm functions that trigger alarms if certain criteria are met. For instance, in one such alarm function, “[t]he [glucose] monitor can . . . determine a prediction of the ‘morning glucose’ level at wake up based upon the calculated average blood glucose and the rate of blood glucose change. . . . If the anticipated ‘morning glucose’ level is greater than a high threshold value (<i>e.g.</i>, but not limited to, 126 mg/dL), or less than a low threshold value (<i>e.g.</i>, but not limited to, 60 mg/dL), an alarm is sounded.” (612 Publication at ¶ 0069.) The 612 Publication further teaches that “[i]n some embodiments, the triggering criteria can also be parameterized to allow the user to customize the values. Accordingly, in</p>

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Claim 19	Exemplary Disclosure
	<p>some embodiments, the user is allowed to set the values for the controlling parameters. For example, the user can set the qualifying low and high glucose levels as well as the anticipated waking time.” (<i>Id.</i> at ¶ 0070.) Alternatively, “[f]or each of the settings a default value can be used in the absence of a user setting. For example, a default low glucose level of 60 mg/dL, a default high glucose level of 126 mg/dL and an anticipated waking time of 7:00 AM can be used. In addition, the entire function can be enabled and disabled.” (<i>Id.</i>) The 612 Publication thus teaches evaluating sensor data using a function (<i>i.e.</i>, “morning glucose” level) to determine whether a parameter indicative of a glucose value (anticipated “morning glucose” level) meets one or more non-user settable second criteria (<i>i.e.</i>, default low glucose level).</p> <p>It would have been obvious to a person of ordinary skill in the art (“POSITA”) to add the “morning glucose” level function from the 612 Publication to the system described in the 764 Provisional. Both references disclose systems for monitoring glucose levels in a patient using an implantable glucose monitor and outputting an alert to inform a patient if his or her glucose level—or another parameter indicative of glucose level—reaches some dangerous threshold. A POSITA would have been motivated to improve the on-skin control unit disclosed in the 764 Provisional by incorporating the 612 Publication’s non-user settable morning glucose alarm, which would allow a patient to have increased notice of potential hypoglycemic events and better avoid them.</p> <p>Similarly, Dexcom’s STS User’s Guide, published in 2006, discloses a continuous glucose monitoring system with two hypoglycemic alarms. The first alarm (called an “alert” in the User’s guide) is configured to alert the user when the user’s glucose level passes a user-settable threshold. The user may “select high and low glucose alerts that will tell [the user] when [her or his] glucose values are out of [the] target range.” (Dexcom STS User’s Guide at p. 54.) The user “use[s] the Up ▲ or Down ▼ Arrows to increase or decrease the low glucose alert value by 10 mg/dL.” (<i>Id.</i> at 78.)</p>

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Claim 19	Exemplary Disclosure
	<div data-bbox="758 277 1692 375"> 4.2 RESPONDING TO HIGH AND LOW GLUCOSE ALERTS </div> <p data-bbox="758 383 1692 643">One of the benefits of the DexCom™ STS™ System is your ability to select high and low glucose alerts that will tell you when your glucose values are out of your target range (see Section 7.3). This feature is especially helpful during extended periods of time when you may not test your blood glucose (such as sleeping, driving, exercise, or long meetings).</p> <ul data-bbox="758 651 1692 984" style="list-style-type: none"> • When your STS Sensor glucose values are below your Low Alert setting and trending down, the STS Receiver will vibrate and display the Low Alert Screen. • When the STS Sensor glucose values are above your High Alert setting and trending up, the STS Receiver will vibrate and display the High Alert Screen. • Examples of the STS Receiver Screens are shown below: <div data-bbox="911 1005 1205 1187"> <p>The screen displays a large downward-pointing triangle on the left. To its right is the number '80' inside a square, followed by 'mg/dL' and a horizontal line. Below these elements, the word 'LOW' is displayed in large, bold, capital letters.</p> </div> <p data-bbox="936 1195 1180 1219">Low Glucose Alert Screen</p> <div data-bbox="1247 1005 1541 1187"> <p>The screen displays a large upward-pointing triangle on the left. To its right is the number '200' inside a square, followed by 'mg/dL' and a horizontal line. Above these elements, the word 'HIGH' is displayed in large, bold, capital letters.</p> </div> <p data-bbox="1272 1195 1516 1219">High Glucose Alert Screen</p>

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Claim 19	Exemplary Disclosure
	<ul style="list-style-type: none"> • Once you press OK to select your high glucose alert value, you will see the Low Glucose Alert Screen: <div data-bbox="1087 378 1360 550" data-label="Image"> </div> <ul style="list-style-type: none"> • Use the Up ▲ or Down ▼ Arrows to increase or decrease the low glucose alert value by 10 mg/dL. • You may select low glucose alert values from 60 mg/dL to 90 mg/dL. Select the value recommended by your Diabetes Management Team by pressing the OK Button. <p>(<i>Id.</i> at 54, 78-79.)</p> <p>“In addition to [the] personal glucose alert settings, [the] STS™ Receiver also has an automatic low glucose alarm set at 55mg/dL (3.1 mmol/L).” (<i>Id.</i> at 56.) The user “cannot change or turn off the Low Glucose Alarm.” (<i>Id.</i>)</p>

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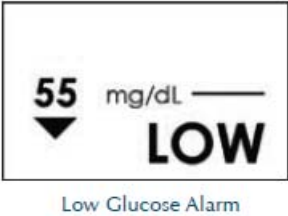
Claim 19	Exemplary Disclosure
	<div data-bbox="768 277 1684 326" data-label="Section-Header"><h4>4.3 LOW GLUCOSE ALARM</h4></div> <p data-bbox="768 383 1684 508">In addition to your personal glucose alert settings, your STS™ Receiver also has an automatic low glucose alarm set at 55mg/dL (3.1 mmol/L). You cannot change or turn off the Low Glucose Alarm.</p> <ul data-bbox="768 526 1684 651" style="list-style-type: none">• When the STS Sensor detects a glucose level below 55 mg/dL (3.1 mmol/L) your STS Receiver will vibrate to notify you of a very low glucose value by displaying the following screen: <div data-bbox="1077 675 1362 889" data-label="Image">A screenshot of a digital display showing a low glucose alarm. The text '55 mg/dL' is displayed with a downward-pointing triangle to its left. Below this, the word 'LOW' is shown in large, bold, capital letters. The entire display is enclosed in a thin black rectangular border.</div> <p data-bbox="562 898 621 930"><i>(Id.)</i></p> <p data-bbox="562 971 1856 1112">The Dexcom STS User's Guide thus discloses a system that evaluates sensor data using a "second function" (<i>i.e.</i>, "automatic low glucose alarm") to determine whether a parameter indicative of a glucose value (in this case, the user's glucose level) meets one or more non-user settable criteria (<i>i.e.</i>, the Low Glucose Alarm level).</p> <p data-bbox="562 1153 1885 1404">It would have been obvious to a POSITA to combine the teachings of the Dexcom STS User's Guide with the teachings of the 764 Provisional. Both references disclose systems for monitoring glucose levels in a patient using an implantable glucose monitor and outputting an alert to inform a patient if his or her glucose level—or another parameter indicative of glucose level—reaches a dangerous threshold. A POSITA would have been motivated to incorporate the non-user settable Low Glucose Alarm from the STS User's Guide into the alarm system of the 764 Provisional's on-skin control unit to ensure that a patient is made aware of dangerous hypoglycemic events.</p>

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Claim 19	Exemplary Disclosure
	<p>Thus, to the extent not disclosed in the 764 Provisional, evaluating sensor data using a second function to determine whether a parameter indicative of a glucose value meets one or more non-user settable second criteria is merely an obvious variant of the subject matter of the 764 Provisional, alone or in view of the 612 Publication and/or Dexcom STS User's Guide.</p>
<p>[19e] activate a first hypoglycemic indicator if the one or more user settable first criteria is met</p>	<p>The 764 Provisional discloses this subject matter. As discussed with respect to element 19c above, the ADC 509 Patent, appended to and incorporated by reference into the 764 Provisional, discloses evaluating sensor data (<i>i.e.</i>, “data from the processing circuit 109”) using a first function (<i>i.e.</i>, “alarm system 104”) to determine whether a real time glucose value meets one or more user settable first criteria (<i>i.e.</i>, “threshold values” that “may be programmable by a patient and/or a medical professional”).</p> <p>In addition, the ADC 509 Patent discloses that the transcutaneous “alarm system 104 <i>may contain one or more individual alarms. Each of the alarms may be individually activated to indicate one or more conditions of the analyte.</i> The alarms may be, for example, auditory or visual. Other sensory-stimulating alarm systems may be used including alarm systems which heat, cool, vibrate, or produce a mild electrical shock when activated.” (764 Provisional at D-213 (ADC 509 Patent at 46:9–15).) An auditory alarm might use “a different tone, note, or volume indicating different conditions. For example, a high note might indicate hyperglycemia and a low note might indicate hypoglycemia.” (<i>Id.</i> (ADC 509 Patent at 46:15–19).) In addition, the auditory alarm can be configured “so that the volume of the alarm increases over time until the alarm is deactivated.” (<i>Id.</i> (ADC 509 Patent at 46:21–23).) A visual alarm, on the other hand, “may use a difference in color, brightness, or position on the on-skin sensor control device 44 to indicate different conditions.” (<i>Id.</i> (ADC 509 Patent at 46:19–21).)</p> <p>Thus, the 764 Provisional at least through appending and incorporating by reference the ADC 509 Patent, discloses activating a first hypoglycemic indicator (<i>i.e.</i>, “one or more individual alarms”) if the one or more user settable first criteria is met (<i>i.e.</i>, if “blood glucose levels” exceed “threshold values” that “may be programmable by a patient and/or a medical professional”).</p>

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Claim 19	Exemplary Disclosure
<p>[19f] and activate a second hypoglycemic indicator if the one or more non user settable second criteria are met; and</p>	<p>The 764 Provisional discloses this subject matter. As discussed with respect to element 19d above, the ADC 509 Patent, appended to and incorporated by reference into the 764 Provisional—alone or in combination with the 612 Publication or the Dexcom STS User’s Guide—discloses evaluating sensor data (<i>i.e.</i>, “data from the processing circuit 109”) using a second function (<i>i.e.</i>, “alarm system 104” function that compares “rate of change in glucose concentration” to a “threshold value” [from the ADC 509 Patent]; the “morning glucose” level [from the 612 Publication]; or the “automatic low glucose alarm” [from the Dexcom STS User’s Guide]) to determine whether a parameter indicative of a glucose value (<i>i.e.</i>, “rate of change in glucose concentration” [from the ADC 509 Patent]; anticipated “morning glucose” level [from the 612 Publication]; or the user’s glucose level [from the Dexcom STS User’s Guide]) meets one or more non-user settable second criteria (<i>i.e.</i>, “threshold values” that “may”—or <i>may not</i>—“be programmable by a patient and/or a medical professional” [from the ADC 509 Patent]; the default low glucose level [from the 612 Publication]; or the Low Glucose Alarm level [from the Dexcom STS User’s Guide]).</p> <p>In addition, the ADC 509 Patent discloses that the transcutaneous “alarm system 104 <i>may contain one or more individual alarms. Each of the alarms may be individually activated to indicate one or more conditions of the analyte.</i> The alarms may be, for example, auditory or visual. Other sensory-stimulating alarm systems may be used including alarm systems which heat, cool, vibrate, or produce a mild electrical shock when activated.” (764 Provisional at D-213 (ADC 509 Patent at 46:9–15).) An auditory alarm might use “a different tone, note, or volume indicating different conditions. For example, a high note might indicate hyperglycemia and a low note might indicate hypoglycemia.” (<i>Id.</i> (ADC 509 Patent at 46:15–19).) In addition, the auditory alarm can be configured “so that the volume of the alarm increases over time until the alarm is deactivated.” (<i>Id.</i> (ADC 509 Patent at 46:21–23).) A visual alarm, on the other hand, “may use a difference in color, brightness, or position on the on-skin sensor control device 44 to indicate different conditions.” (<i>Id.</i> (ADC 509 Patent at 46:19–21).)</p> <p>Thus, the 764 Provisional at least through appending and incorporating by reference the ADC 509 Patent—alone or in combination with the 612 Publication or the Dexcom STS User’s Guide—discloses activating a second hypoglycemic indicator (<i>i.e.</i>, “one or more individual alarms”) if the one or more non-user settable second criteria (<i>i.e.</i>, “threshold values” that “may”—or <i>may not</i>—“be programmable by a patient and/or a medical professional” [from the ADC 509 Patent]; the default low glucose level</p>

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Claim 19	Exemplary Disclosure
	[from the 612 Publication]; sor the Low Glucose Alarm level [from the Dexcom STS User's Guide]) is met.
[19g] provide an output based on the activated hypoglycemic indicator.	<p>The 764 Provisional discloses this subject matter. The ADC 509 Patent, appended to and incorporated by reference into the 764 Provisional, discloses that the transcutaneous “alarm system 104 <i>may contain one or more individual alarms. Each of the alarms may be individually activated to indicate one or more conditions of the analyte.</i> The alarms may be, for example, auditory or visual. Other sensory-stimulating alarm systems may be used including alarm systems which heat, cool, vibrate, or produce a mild electrical shock when activated.” (764 Provisional at D-213 (ADC 509 Patent at 46:9–15).) An auditory alarm might use “a different tone, note, or volume <i>indicating different conditions.</i> For example, <i>a high note might indicate hyperglycemia and a low note might indicate hypoglycemia.</i>” (<i>Id.</i> (ADC 509 Patent at 46:15–19).) A visual alarm, on the other hand, “<i>may use a difference in color, brightness, or position on the on-skin sensor control device 44 to indicate different conditions.</i>” (<i>Id.</i> (ADC 509 Patent at 46:19–21).)</p> <p>Thus, the 764 Provisional at least through appending and incorporating by reference the ADC 509 Patent, discloses providing an output (<i>e.g.</i>, alarms that “may be, for example, auditory or visual”) based on the activated hypoglycemic indicator (<i>e.g.</i>, “a high note might indicate hyperglycemia and a low note might indicate hypoglycemia”).</p>

EXHIBIT 9

EXHIBIT N

Exhibit N

Claim Chart for U.S. Patent No. 10,702,193

Asserted Patent:

- U.S. Pat. No. 10,702,193 (“193 Patent”) (Ex. S)
 - Filing date: January 14, 2020
 - Earliest claimed priority date: April 15, 2005

Patent or Patent Application Captured in Subsection (a) of Paragraph A.13:

- PCT/US2004/023455, published as WO 2005/010518 (“518 Publication”) (Ex. E)
 - Filing date: July 21, 2004

Including references incorporated by reference¹:

- U.S. Appl. No. 10/789,359, published as U.S. Publ. No. 2005/0192557 A1 (“557 Publication”) (Ex. T)
 - Filing date: February 26, 2004
- U.S. Appl. No. 60/490,208 (“208 Provisional”) (Ex. U)
 - Filing date: July 25, 2003
- PCT/US2004/040476, published as WO 2005/057168 (“168 Publication”) (Ex. F)
 - Filing date: December 3, 2004

Including references incorporated by reference:

- U.S. Appl. No. 10/896,637, published as U.S. Publ. No. 2005/0051427 A1 (“427 Publication”) (Ex. V)
 - Filing date: July 21, 2004

¹ “When a document is ‘incorporated by reference’ into a host document, such as a patent, the referenced document becomes effectively part of the host document as if it were explicitly contained therein.” *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1329 (Fed. Cir. 2001).

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Claim Chart for U.S. Patent No. 10,702,193

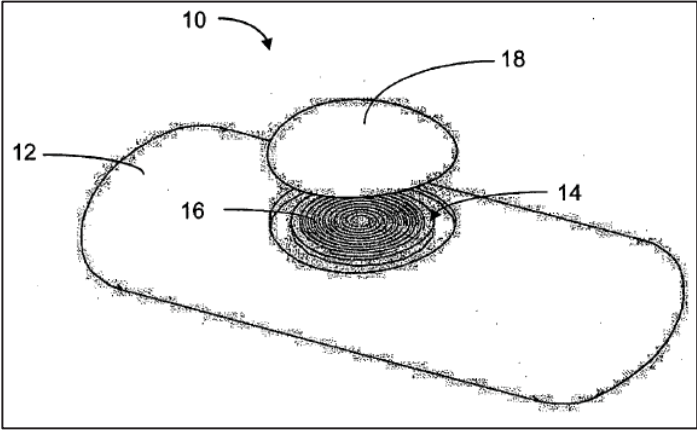
Claim 1	Exemplary Disclosure from 518 Publication	Exemplary Disclosure from 168 Publication
<p>[1Pre] A transcutaneous continuous glucose sensor system comprising:</p>	<p>To the extent the preamble is limiting, the 518 Publication discloses this subject matter. The 518 Publication relates to “electrode arrays for use in electrochemical devices and their method for manufacture.” (518 Publication at ¶ 0001.) The disclosed electrode arrays “can be used in electrochemical applications performed with electrodes such as analyte detection,” and “can be used with any of a variety of known <i>in vitro</i> or <i>in vivo</i> analyte sensors or monitors” (<i>Id.</i> at ¶ 0102.) “[T]he analyte for measurement by the sensing regions, devices, and methods is glucose.” (<i>Id.</i> at ¶ 0095.) For example, the embodiment of Fig. 1 is directed to “an implantable glucose sensor (10) that utilizes amperometric electrochemical sensor technology to measure glucose.” (<i>Id.</i> at ¶ 0103.)</p>  <p>(518 Publication at Fig. 1.)</p>	<p>To the extent the preamble is limiting, the 168 Publication discloses this subject matter. The 168 Publication relates to “systems and methods for processing analyte sensor data.” (168 Publication at ¶ 0002.) The 168 Publication discloses a “continuous analyte sensor that measures a concentration of the analyte of interest or a substance indicative of the concentration or presence of the analyte[,]” wherein “the analyte sensor is an invasive, minimally invasive, or non-invasive device, for example a subcutaneous, transdermal, or intravascular device.” (<i>Id.</i> at ¶ 0061.)</p> <p>The 168 Publication also discloses that “[i]n some embodiments, the analyte for measurement by the sensor heads, devices, and methods disclosed herein is glucose.” (168 Publication at ¶ 0022.)</p> <p>Moreover, “Fig. 1B is an expanded view of an alternative exemplary embodiment of a continuous analyte sensor 10b, also referred to as a transcutaneous analyte sensor,” which “includes three electrodes[,]” including “a glucose-measuring working electrode 16” (168 Publication at ¶ 0074.)</p>

Exhibit N

Claim Chart for U.S. Patent No. 10,702,193

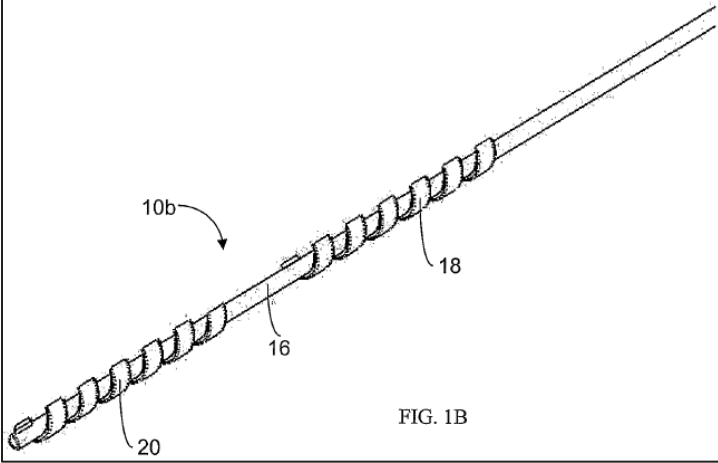
Claim 1	Exemplary Disclosure from 518 Publication	Exemplary Disclosure from 168 Publication
	<p>Moreover, the 518 Publication teaches that “[e]lectrochemical sensors are useful in chemistry and medicine to determine the presence and concentration of a biological analyte. Such sensors are useful, for example, to monitor glucose in diabetic patients and lactate during critical care events.” (518 Publication at ¶ 0002.)</p> <p>The 518 Publication further discloses (and incorporates by reference) patents and applications “that are suitable for use in conjunction with aspects of the preferred embodiments.” (518 Publication at (¶ 0149).) One such application is U.S. Appl. No. 10/789,359, which was thereafter published as U.S. Publ. No. 2005/0192557 A1 (“557 Publication”). (<i>Id.</i>) The 557 Publication discloses an embodiment where “the continuous glucose sensor comprises a transcutaneous sensor” (557 Publication at ¶ 0107.) Another such application is U.S. Appl. No. 60/490,208 (“208 Provisional”). The 208 Provisional discloses “the use of a sensor that measures a concentration of an analyte of interest or a substance indicative of the concentration or presence of the analyte in bodily fluid. In some embodiments, the sensor is a continuous device, for example, a subcutaneous, transdermal, or intravascular device.” (208 Provisional at 005 (¶ 0014).)</p> <p>Therefore, the 518 Publication discloses a transcutaneous continuous glucose sensor system.</p>	 <p>(168 Publication at Fig. 1B.)</p> <p>Therefore, the 168 Publication discloses a transcutaneous continuous glucose sensor system.</p>
[1a] a substantially	The 518 Publication discloses this subject matter. As discussed with respect to element 1Pre above, the 518	The 168 Publication discloses this subject matter. The 168 Publication discloses “a transcutaneous analyte

Exhibit N

Claim Chart for U.S. Patent No. 10,702,193

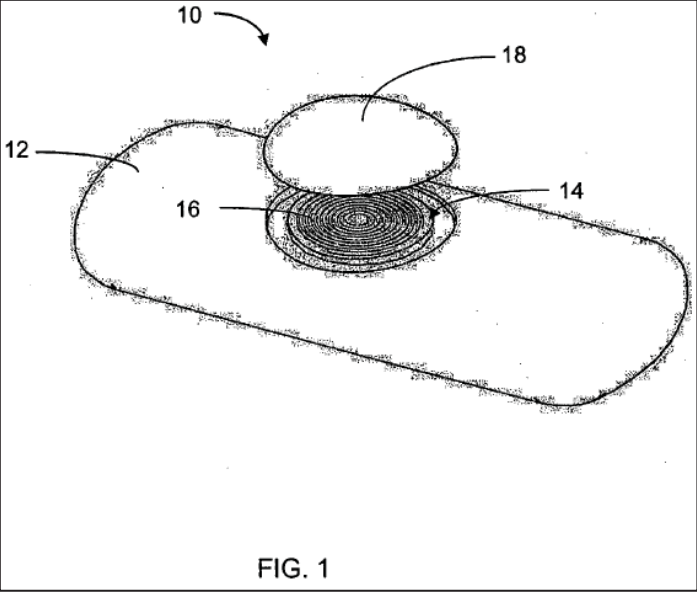
Claim 1	Exemplary Disclosure from 518 Publication	Exemplary Disclosure from 168 Publication
<p>planar sensor, the sensor comprising:</p>	<p>Publication relates to “electrode arrays for use in electrochemical devices and their method for manufacture.” (518 Publication at ¶ 0001.) The “electrode array can be used with any of a variety of known <i>in vitro</i> or <i>in vivo</i> analyte sensors or monitors . . .” (<i>Id.</i> at ¶ 0102.) For example, “Fig. 1 is an exploded perspective view of one exemplary embodiment comprising an implantable glucose sensor (10) that utilizes amperometric electrochemical sensor technology to measure glucose.” (<i>Id.</i> at ¶ 0103.)</p>  <p>FIG. 1</p> <p>(518 Publication at Fig. 1.)</p> <p>Moreover, the 518 Publication provides “[m]ethods for manufacturing electrode arrays suitable for electrochemical applications using bulk materials</p>	<p>sensor” that “includes three electrodes . . .” (168 Publication at ¶ 0074.) The 168 Publication also teaches “the electrodes may be deposited on a substrate or other known configurations as is appreciated by one skilled in the art.” (<i>Id.</i> at ¶ 0075.)</p> <p>The 168 Publication states “[m]ethods and devices that are suitable for use in conjunction with aspects of the preferred embodiments are disclosed in . . . U.S. Appl. No. 10/896,637 filed July 21, 2004 and entitled ‘ROLLED ELECTRODE ARRAY AND ITS METHOD FOR MANUFACTURE[,]’” (168 Publication at ¶ 0142), which was thereafter published as U.S. Publ. No. 2005/0051427 A1 (hereinafter “427 Publication”). The 168 Publication incorporates the 427 Publication by reference. (<i>Id.</i> at ¶ 0142.)</p> <p>The 427 Publication discloses “electrode arrays for use in electrochemical devices and their method for manufacture.” (427 Publication at ¶ 0002.) The “electrode array can be used with any of a variety of known <i>in vitro</i> or <i>in vivo</i> analyte sensors or monitors . . .” (<i>Id.</i> at ¶ 0105.) For example, “Fig. 1 is an exploded perspective view of one exemplary embodiment comprising an implantable glucose sensor (10) that utilizes amperometric electrochemical sensor technology to measure glucose.” (<i>Id.</i> at ¶ 0106.)</p>

Exhibit N

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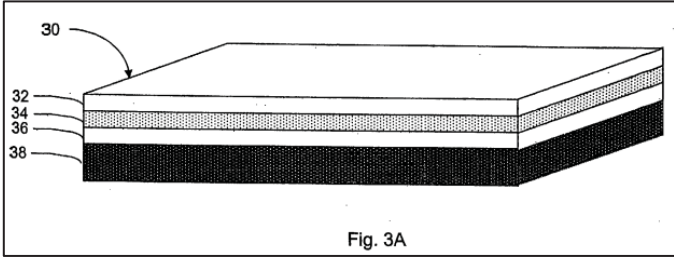
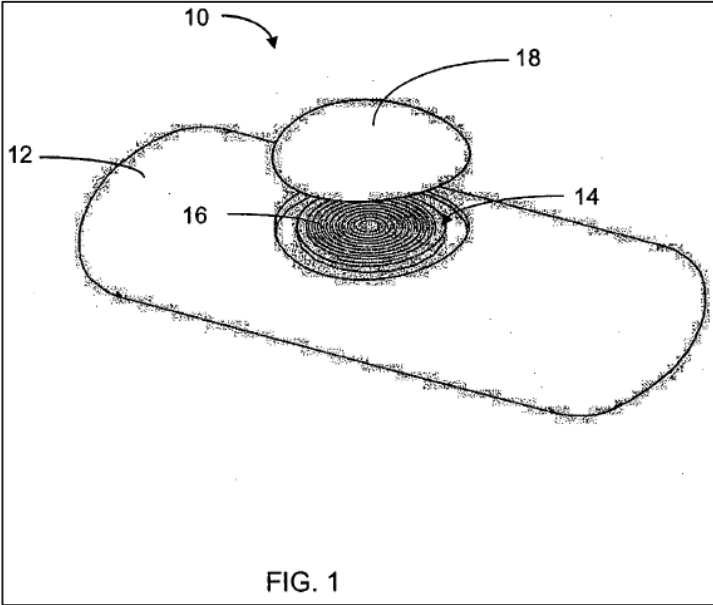
Claim 1	Exemplary Disclosure from 518 Publication	Exemplary Disclosure from 168 Publication
	<p>and/or efficient processes . . .” (518 Publication at ¶ 0116.) While one process of manufacturing electrodes includes “rolling a composite stack of electrode and insulating materials, after which the roll can be cut in a variety of cross-sections to form a variety of electrode array configurations, shapes, and thicknesses,” (<i>id.</i> at ¶ 0116), “the electrode array can be cut or machined without rolling the composite stack, and that portion of the composite stack can be used as the electrode array.” (<i>Id.</i> at ¶ 0144.)</p> <p>For example, “Fig. 3A is [a] perspective view of a stack of materials used in the manufacture of an electrode system of one embodiment. In this embodiment, the composite stack (30) comprises a first insulating layer (32), a first electrode layer (34), a second insulating layer (36), and a second electrode layer (38).” (<i>Id.</i> at ¶ 0117.)</p>  <p style="text-align: center;">Fig. 3A</p> <p>(518 Publication at Fig. 3A.) Thus, the 518 Publication discloses a substantially planar composite stack. (<i>Id.</i>)</p> <p>Moreover, even when the electrode array is rolled, the 518 Publication expressly states that the end configuration can be substantially planar: “The electrode array according to any one of the preceding</p>	 <p style="text-align: center;">FIG. 1</p> <p>(427 Publication at Fig. 1).)</p> <p>Moreover, the 427 Publication provides “[m]ethods for manufacturing electrode arrays suitable for electrochemical applications using bulk materials and/or efficient processes . . .” (427 Publication at ¶ 0120.) While one process of manufacturing electrodes includes “rolling a composite stack of electrode and insulating materials, after which the roll can be cut in a variety of cross-sections to form a variety of electrode array configurations, shapes, and thicknesses,” (<i>id.</i> at ¶ 0120), “the electrode array can be cut or machined without rolling the composite stack, and that portion of the composite stack can be used as the electrode array.” (<i>Id.</i> at ¶ 0149.)</p>

Exhibit N

Claim Chart for U.S. Patent No. 10,702,193

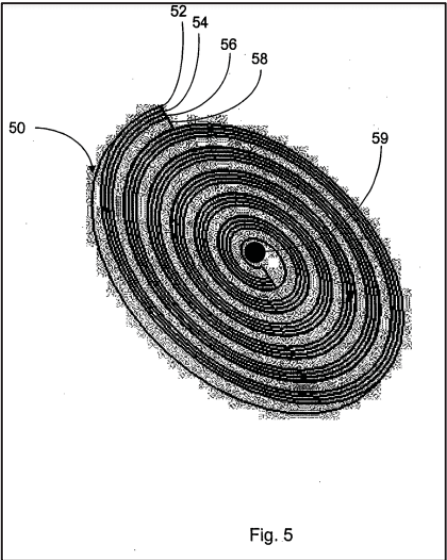
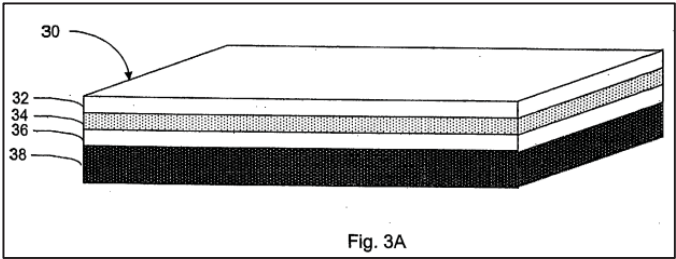
Claim 1	Exemplary Disclosure from 518 Publication	Exemplary Disclosure from 168 Publication
	<p>claims, wherein the electrode array comprises a substantially planar surface.” (See 518 Publication at Claim 11; <i>see also, id.</i> at ¶ 0033 (“In an aspect of the first embodiment, the electrode array includes a substantially planar surface.”).) For example, “Figure 5 is a perspective view of an electrode array that is formed by slicing along a plane perpendicular to the longitudinal axis of the spiral roll.” (<i>Id.</i> at ¶ 0087.)</p>  <p style="text-align: center;">Fig. 5</p> <p>(518 Publication at Fig. 5.)</p> <p>The 518 Publication thus discloses a substantially planar sensor having a construction that is (i) layers of stacked electrodes and insulators as depicted in Figure 3A or (ii) layers of stacked electrodes and insulators that have been rolled, and then sliced into planar</p>	<p>For example, “Fig. 3A is [a] perspective view of a stack of materials used in the manufacture of an electrode system of one embodiment. In this embodiment, the composite stack (30) comprises a first insulating layer (32), a first electrode layer (34), a second insulating layer (36), and a second electrode layer (38).” (427 Publication at ¶ 0121.)</p>  <p style="text-align: center;">Fig. 3A</p> <p>(427 Publication at Fig. 3A.) Thus, the 427 Publication discloses a substantially planar composite stack. (<i>Id.</i> at Fig. 3A.)</p> <p>Moreover, even when the electrode array is rolled, the 427 Publication expressly states that the end configuration can be substantially planar: “The electrode array of claim 1, wherein the electrode array comprises a substantially planar surface.” (427 Publication at Claim 29; <i>see also, id.</i> at ¶ 0034 (“In an aspect of the first embodiment, the electrode array includes a substantially planar surface.”).) For example, “Figure 5 is a perspective view of an electrode array that is formed by slicing along a plane perpendicular to the longitudinal axis of the spiral roll.” (<i>Id.</i> at ¶ 0088.)</p>

Exhibit N

Claim Chart for U.S. Patent No. 10,702,193

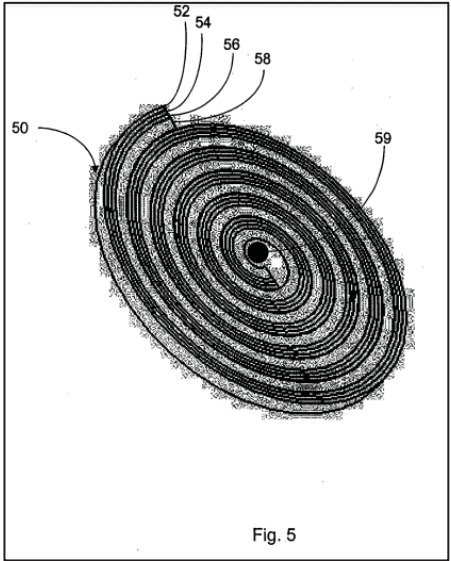
Claim 1	Exemplary Disclosure from 518 Publication	Exemplary Disclosure from 168 Publication
	surfaces as depicted in Figure 5. Therefore, the 518 Publication discloses a substantially planar sensor.	<div data-bbox="1312 245 1759 803">  <p>Fig. 5</p> </div> <p>(427 Publication at Fig. 5.)</p> <p>The 427 Publication thus discloses a substantially planar sensor having a construction that is (i) layers of stacked electrodes and insulators as depicted in Figure 3A or (ii) layers of stacked electrodes and insulators that have been rolled, and then sliced into planar surfaces as depicted in Figure 5. Therefore, through incorporation by reference of the 427 Publication, the 168 Publication discloses a substantially planar sensor.</p>
[1b] a first conductive layer associated with	The 518 Publication discloses this subject matter. As noted above with respect to element 1a, “Fig. 3A is [a] perspective view of a stack of materials used in the manufacture of an electrode system of one embodiment. In this embodiment, the composite stack (30) comprises	The 168 Publication discloses this subject matter. As noted above with respect to element 1a, Fig. 3A of the 427 Publication, incorporated by reference into the 168 Publication, “is [a] perspective view of a stack of materials used in the manufacture of an electrode

Exhibit N

Claim Chart for U.S. Patent No. 10,702,193

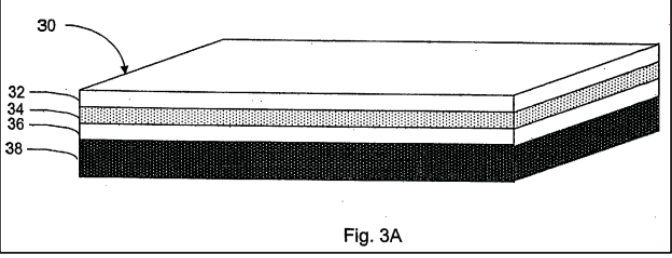
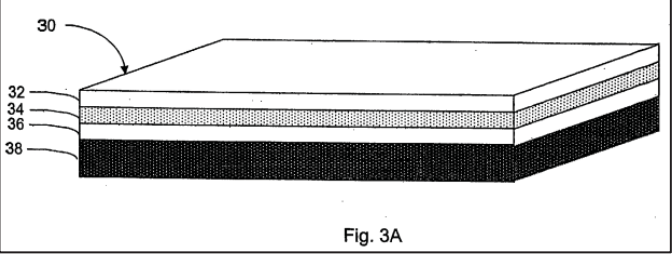
Claim 1	Exemplary Disclosure from 518 Publication	Exemplary Disclosure from 168 Publication
<p>a first electrode;</p>	<p>a first insulating layer (32), a first electrode layer (34), a second insulating layer (36), and a second electrode layer (38).” (518 Publication at ¶ 0117.)</p>  <p>Fig. 3A</p> <p>(518 Publication at Fig. 3A.)</p> <p>The 518 Publication further teaches that the electrode layers “can comprise any suitable metal or conductive polymer electrode material” (518 Publication at ¶ 0125.) Thus, the electrode layer (38) of Figure 3A is a first conductive layer associated with a first electrode. (<i>See id.</i> at Fig. 3A.)</p> <p>Moreover, as also noted above with respect to element 1a, “Figure 5 is a perspective view of an electrode array that is formed by slicing along a plane perpendicular to the longitudinal axis of the spiral roll.” (518 Publication at ¶ 0087.) The electrode array depicted in Figure 5 “includes first insulating layer (52), a working electrode layer (54), a second insulating layer (56), a counter electrode layer (58)” (<i>Id.</i> at ¶ 0136.)</p> <p>Further, as explained above, the 518 Publication teaches that the electrode layers “can comprise any suitable metal or conductive polymer electrode material” (<i>Id.</i> at ¶ 0125.) Thus, the counter electrode layer (58) of</p>	<p>system of one embodiment. In this embodiment, the composite stack (30) comprises a first insulating layer (32), a first electrode layer (34), a second insulating layer (36), and a second electrode layer (38).” (427 Publication at ¶ 0121.)</p>  <p>Fig. 3A</p> <p>(427 Publication at Fig. 3A.)</p> <p>The 427 Publication further teaches that the electrode layers “can comprise any suitable metal or conductive polymer electrode material” (427 Publication at ¶ 0129.) Thus, the electrode layer (38) of Figure 3A is a first conductive layer associated with a first electrode. (<i>See id.</i> at Fig. 3A.)</p> <p>Moreover, as also noted above with respect to element 1a, “Figure 5 is a perspective view of an electrode array that is formed by slicing along a plane perpendicular to the longitudinal axis of the spiral roll.” (427 Publication at ¶ 0088.) The electrode array depicted in Figure 5 “includes first insulating layer (52), a working electrode layer (54), a second insulating layer (56), a counter electrode layer (58)” (<i>Id.</i> at ¶ 0141.)</p> <p>Further, as explained above, the 427 Publication teaches that the electrode layers “can comprise any suitable metal or conductive polymer electrode material”</p>

Exhibit N

Claim Chart for U.S. Patent No. 10,702,193

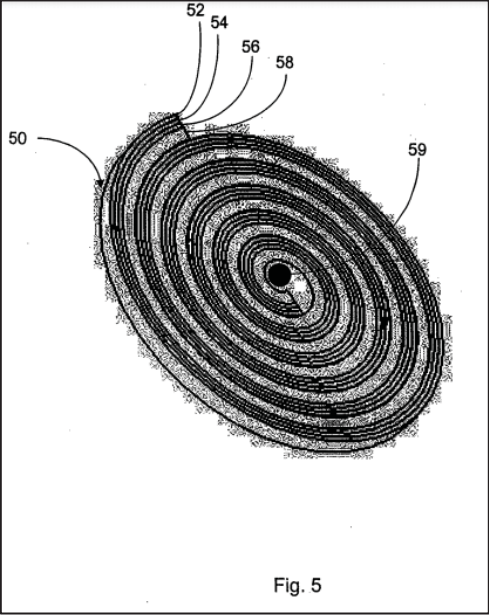
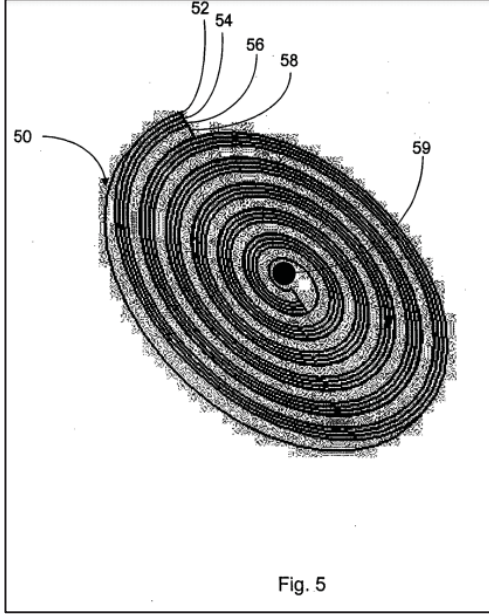
Claim 1	Exemplary Disclosure from 518 Publication	Exemplary Disclosure from 168 Publication
	<p>Figure 5 is a first conductive layer associated with a first electrode. (See <i>id.</i> at Fig. 3A.)</p>  <p style="text-align: center;">Fig. 5</p> <p>(518 Publication at Fig. 5.)</p> <p>Therefore, the 518 Publication discloses a first conductive layer associated with a first electrode (<i>e.g.</i>, the electrode layer (38) of Figure 3A and the counter electrode layer (58) of Figure 5).</p>	<p>(<i>Id.</i> at ¶ 0129.) Thus, the counter electrode layer (58) of Figure 5 is a first conductive layer associated with a first electrode. (See <i>id.</i> at Fig. 3A.)</p>  <p style="text-align: center;">Fig. 5</p> <p>(427 Publication at Fig. 5.)</p> <p>Therefore, through incorporation by reference of the 427 Publication, the 168 Publication discloses a first conductive layer associated with a first electrode (<i>e.g.</i>, the electrode layer (38) of Figure 3A and the counter electrode layer (58) of Figure 5).</p>
[1c] a first non-conductive	The 518 Publication discloses this subject matter. As noted above with respect to element 1a, “Fig. 3A is [a] perspective view of a stack of materials used in the	The 168 Publication discloses this subject matter. As noted above with respect to element 1a, Fig. 3A of the 427 Publication, incorporated by reference into the 168

Exhibit N

Claim Chart for U.S. Patent No. 10,702,193

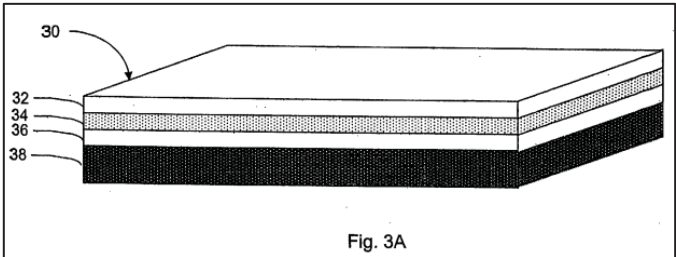
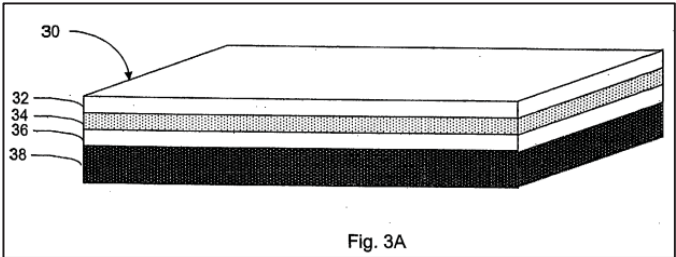
Claim 1	Exemplary Disclosure from 518 Publication	Exemplary Disclosure from 168 Publication
<p>layer located at least in part over the first conductive layer;</p>	<p>manufacture of an electrode system of one embodiment. In this embodiment, the composite stack (30) comprises a first insulating layer (32), a first electrode layer (34), a second insulating layer (36), and a second electrode layer (38).” (518 Publication at ¶ 0117.)</p>  <p>(518 Publication at Fig. 3A.)</p> <p>A person having ordinary skill in the art would have understood that an insulating layer is non-conductive. The 518 Publication teaches that “[a] variety of electrode and insulating materials can be used” and “[t]he insulating layers can comprise polyimide, polyester, polyurethane, perfluorinated polymer, polycarbonate, polyvinyl chloride, high-density polypropylene, low-density polypropylene, Parylene, epoxy, hydrogels, or silicone, for example.” (518 Publication at ¶ 0125.) Accordingly, the insulating layer (36) of Figure 3A is a first non-conductive layer. (<i>See id.</i> at Fig. 3A.)</p> <p>Further, as shown in Figure 3A, the insulating layer (36) (<i>i.e.</i>, “first non-conductive layer”) is located at least in part over the electrode layer (38) (<i>i.e.</i>, “first conductive layer”). (<i>See</i> 518 Publication at Fig. 3A.) Accordingly, the 518 Publication discloses a first non-</p>	<p>Publication, “is [a] perspective view of a stack of materials used in the manufacture of an electrode system of one embodiment. In this embodiment, the composite stack (30) comprises a first insulating layer (32), a first electrode layer (34), a second insulating layer (36), and a second electrode layer (38).” (427 Publication at ¶ 0121.)</p>  <p>(427 Publication at Fig. 3A.)</p> <p>A person having ordinary skill in the art would have understood that an insulating layer is non-conductive. The 427 Publication teaches that “[a] variety of electrode and insulating materials can be used” and “[t]he insulating layers can comprise polyimide, polyester, polyurethane, perfluorinated polymer, polycarbonate, polyvinyl chloride, high-density polypropylene, low-density polypropylene, Parylene, epoxy, hydrogels, or silicone, for example.” (427 Publication at ¶ 0129.) Accordingly, the insulating layer (36) of Figure 3A is a first non-conductive layer. (<i>See id.</i> at Fig. 3A.)</p> <p>Further, as shown in Figure 3A, the insulating layer (36) (<i>i.e.</i>, “first non-conductive layer”) is located at least in part over the electrode layer (38) (<i>i.e.</i>, “first</p>

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Claim Chart for U.S. Patent No. 10,702,193

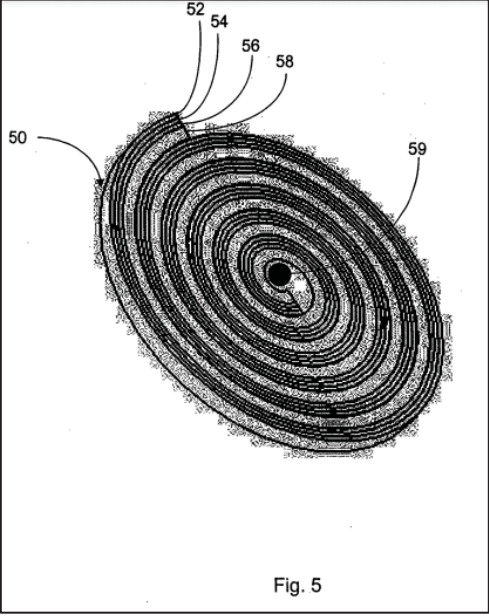
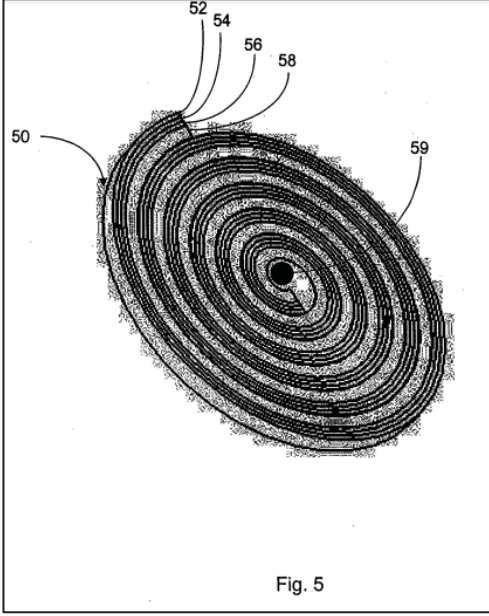
Claim 1	Exemplary Disclosure from 518 Publication	Exemplary Disclosure from 168 Publication
	<p>conductive layer (<i>i.e.</i>, the insulating layer (36) of Figure 3A) located at least in part over the first conductive layer (<i>i.e.</i>, the electrode layer (38) of Figure 3A).</p> <p>Moreover, as also noted above with respect to element 1a, “Figure 5 is a perspective view of an electrode array that is formed by slicing along a plane perpendicular to the longitudinal axis of the spiral roll.” (518 Publication at ¶ 0087.) The electrode array depicted in Figure 5 “includes first insulating layer (52), a working electrode layer (54), a second insulating layer (56), a counter electrode layer (58) ...” (<i>Id.</i> at ¶ 0136.)</p>  <p style="text-align: center;">Fig. 5</p> <p>(518 Publication at Fig. 5.)</p>	<p>conductive layer”). (See 427 Publication at Fig. 3A.) Accordingly, the 427 Publication discloses a first non-conductive layer (<i>i.e.</i>, the insulating layer (36) of Figure 3A) located at least in part over the first conductive layer (<i>i.e.</i>, the electrode layer (38) of Figure 3A).</p> <p>Moreover, as also noted above with respect to element 1a, “Figure 5 is a perspective view of an electrode array that is formed by slicing along a plane perpendicular to the longitudinal axis of the spiral roll.” (427 Publication at ¶ 0088.) The electrode array depicted in Figure 5 “includes first insulating layer (52), a working electrode layer (54), a second insulating layer (56), a counter electrode layer (58) ...” (<i>Id.</i> at ¶ 0141.)</p>  <p style="text-align: center;">Fig. 5</p>

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Claim Chart for U.S. Patent No. 10,702,193

Claim 1	Exemplary Disclosure from 518 Publication	Exemplary Disclosure from 168 Publication
	<p>As explained above, a person having ordinary skill in the art would have understood that an insulating layer is non-conductive. (<i>See, e.g.</i>, 518 Publication at ¶ 0125.) Accordingly, the insulating layer (56) of Figure 5 is a first non-conductive layer. (<i>See id.</i> at Fig. 5.)</p> <p>Further, as shown in Figure 5, the insulating layer (56) (<i>i.e.</i>, “first non-conductive layer”) is located at least in part over the second electrode layer (58) (<i>i.e.</i>, “first conductive layer”). (<i>See</i> 518 Publication at Fig. 5.) Accordingly, the 518 Publication discloses a first non-conductive layer (the insulating layer (56) of Figure 5) located at least in part over the first conductive layer (the electrode layer (58) of Figure 5).</p> <p>Therefore, the 518 Publication discloses a first non-conductive layer located at least in part over the first conductive layer.</p>	<p>(427 Publication at Fig. 5.)</p> <p>As explained above, a person having ordinary skill in the art would have understood that an insulating layer is non-conductive. (<i>See, e.g.</i>, 427 Publication at ¶ 0129.) Accordingly, the insulating layer (56) of Figure 5 is a first non-conductive layer. (<i>See id.</i> at Fig. 5.)</p> <p>Further, as shown in Figure 5, the insulating layer (56) (<i>i.e.</i>, “first non-conductive layer”) is located at least in part over the second electrode layer (58) (<i>i.e.</i>, “first conductive layer”). (<i>See</i> 427 Publication at Fig. 5.) Accordingly, the 427 Publication discloses a first non-conductive layer (the insulating layer (56) of Figure 5) located at least in part over the first conductive layer (the second electrode layer (58) of Figure 5).</p> <p>Therefore, through incorporation by reference of the 427 Publication, the 168 Publication discloses a first non-conductive layer located at least in part over the first conductive layer.</p>
[1d] a second conductive layer associated with a second electrode, wherein the second conductive layer is located at least in part	<p>The 518 Publication discloses this subject matter. As noted above with respect to element 1a, “Fig. 3A is [a] perspective view of a stack of materials used in the manufacture of an electrode system of one embodiment. In this embodiment, the composite stack (30) comprises a first insulating layer (32), a first electrode layer (34), a second insulating layer (36), and a second electrode layer (38).” (518 Publication at ¶ 0117.)</p>	<p>The 168 Publication discloses this subject matter. As noted above with respect to element 1a, Fig. 3A of the 427 Publication, incorporated by reference into the 168 Publication, “is [a] perspective view of a stack of materials used in the manufacture of an electrode system of one embodiment. In this embodiment, the composite stack (30) comprises a first insulating layer (32), a first electrode layer (34), a second insulating layer (36), and a second electrode layer (38).” (427 Publication at ¶ 0121.)</p>

Exhibit N

Claim Chart for U.S. Patent No. 10,702,193

Claim 1	Exemplary Disclosure from 518 Publication	Exemplary Disclosure from 168 Publication
<p>over the first non-conductive layer;</p>	<div data-bbox="457 251 1123 500"> <p>Fig. 3A</p> </div> <p>(518 Publication at Fig. 3A.)</p> <p>As noted above with respect to element 1d, the 518 Publication further discloses that the electrode layers “can comprise any suitable metal or conductive polymer electrode material . . .” (518 Publication at ¶ 0125.) Accordingly, the first electrode layer (34) of Figure 3A is a second conductive layer associated with a second electrode. (<i>See id.</i> at Fig. 3A.)</p> <p>Further, as shown in Figure 3A, the first electrode layer (34) (<i>i.e.</i>, “the second conductive layer”) is located at least in part over the insulating layer (36) (<i>i.e.</i>, “the first non-conductive layer”). (518 Publication at Fig. 3A.) Accordingly, the 518 Publication discloses a second conductive layer (the first electrode layer (34) of Figure 3A) located at least in part over the first non-conductive layer (the insulating layer (36) of Figure 3A).</p> <p>Moreover, as also noted above with respect to element 1a, “Figure 5 is a perspective view of an electrode array that is formed by slicing along a plane perpendicular to the longitudinal axis of the spiral roll.” (518 Publication at ¶ 0087.) The electrode array depicted in Figure 5 “includes first insulating layer (52), a working electrode layer (54), a second insulating layer (56), a</p>	<div data-bbox="1203 251 1869 500"> <p>Fig. 3A</p> </div> <p>(427 Publication Fig. at 3A.)</p> <p>As noted above with respect to element 1d, the 427 Publication further discloses that the electrode layers “can comprise any suitable metal or conductive polymer electrode material . . .” (427 Publication at ¶ 0129.) Accordingly, the first electrode layer (34) of Figure 3A is a second conductive layer associated with a second electrode. (<i>See id.</i> at Fig. 3A.)</p> <p>Further, as shown in Figure 3A, the first electrode layer (34) (<i>i.e.</i>, “the second conductive layer”) is located at least in part over the insulating layer (36) (<i>i.e.</i>, “the first non-conductive layer”). (427 Publication at Fig. 3A.) Accordingly, the 427 Publication discloses a second conductive layer (the first electrode layer (34) of Figure 3A) located at least in part over the first non-conductive layer (the insulating layer (36) of Figure 3A).</p> <p>Moreover, as also noted above with respect to element 1a, “Figure 5 is a perspective view of an electrode array that is formed by slicing along a plane perpendicular to the longitudinal axis of the spiral roll.” (427 Publication at ¶ 0088.) The electrode array depicted in Figure 5 “includes first insulating layer (52), a working electrode layer (54), a second insulating layer (56), a</p>

Exhibit N

Claim Chart for U.S. Patent No. 10,702,193

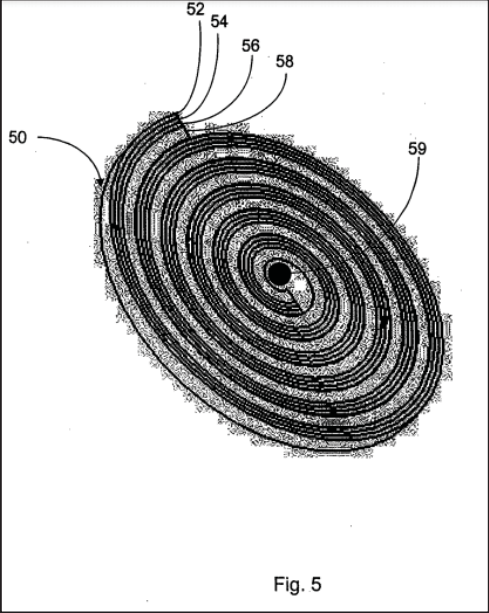
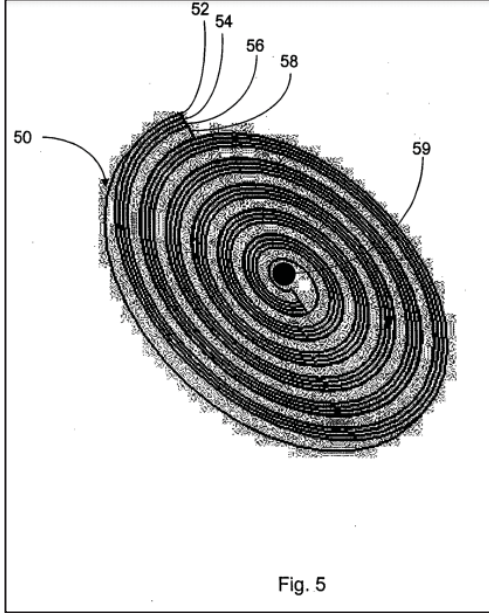
Claim 1	Exemplary Disclosure from 518 Publication	Exemplary Disclosure from 168 Publication
	<p>counter electrode layer (58) ...” (<i>Id.</i> at ¶ 0136.) Further, as explained above, the 518 Publication teaches that the electrode layers “can comprise any suitable metal or conductive polymer electrode material” (<i>Id.</i> at ¶ 0125.) Thus, the working electrode layer (54) of Figure 5 is a second conductive layer associated with a second electrode. (<i>See id.</i> at Fig. 5.)</p>  <p style="text-align: center;">Fig. 5</p> <p>(518 Publication at Fig. 5.)</p> <p>Further, as shown in Figure 5, the working electrode layer (54) (<i>i.e.</i>, “second conductive layer”) is located at least in part over the insulating layer (56) (<i>i.e.</i>, “first non-conductive layer”). (<i>See</i> 518 Publication at Fig. 5.) Accordingly, the 518 Publication discloses a second conductive layer (the working electrode layer (54) of</p>	<p>counter electrode layer (58) ...” (<i>Id.</i> at ¶ 0141.) Further, as explained above, the 427 Publication teaches that the electrode layers “can comprise any suitable metal or conductive polymer electrode material” (<i>Id.</i> at ¶ 0129.) Thus, the working electrode layer (54) of Figure 5 is a second conductive layer associated with a second electrode. (<i>See id.</i> at Fig. 5.)</p>  <p style="text-align: center;">Fig. 5</p> <p>(427 Publication at Fig. 5.)</p> <p>Further, as shown in Figure 5, the working electrode layer (54) (<i>i.e.</i>, “second conductive layer”) is located at least in part over the insulating layer (56) (<i>i.e.</i>, “first non-conductive layer”). (<i>See</i> 427 Publication at Fig. 5.) Accordingly, the 427 Publication discloses a second conductive layer (the working electrode layer (54) of</p>

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Claim Chart for U.S. Patent No. 10,702,193

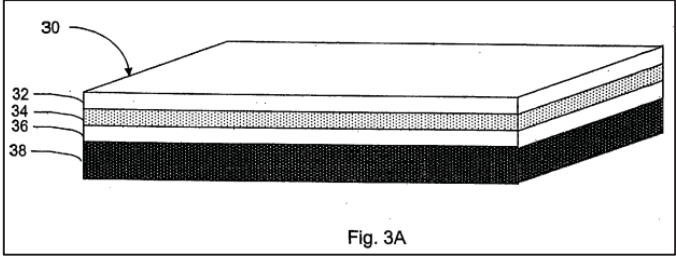
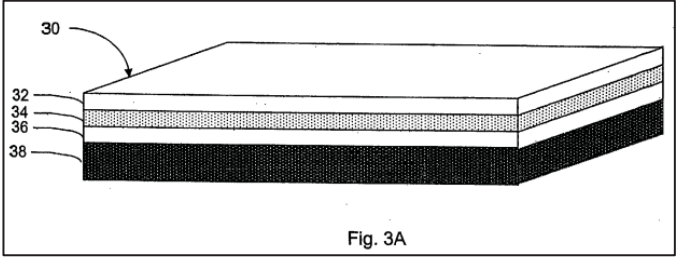
Claim 1	Exemplary Disclosure from 518 Publication	Exemplary Disclosure from 168 Publication
	<p>Figure 5) located at least in part over the first non-conductive layer (the insulating layer (56) of Figure 5).</p> <p>Therefore, the 518 Publication discloses a second conductive layer associated with a second electrode, wherein the second conductive layer is located at least in part over the first non-conductive layer.</p>	<p>Figure 5) located at least in part over the first non-conductive layer (the insulating layer (56) of Figure 5).</p> <p>Therefore, through incorporation by reference of the 427 Publication, the 168 Publication discloses a second conductive layer associated with a second electrode, wherein the second conductive layer is located at least in part over the first non-conductive layer.</p>
<p>[1e] a second non-conductive layer located at least in part over the second conductive layer;</p>	<p>The 518 Publication discloses this subject matter. As noted above with respect to element 1a, “Fig. 3A is [a] perspective view of a stack of materials used in the manufacture of an electrode system of one embodiment. In this embodiment, the composite stack (30) comprises a first insulating layer (32), a first electrode layer (34), a second insulating layer (36), and a second electrode layer (38).” (518 Publication at ¶ 0117.)</p>  <p>(518 Publication at Fig. 3A.)</p> <p>As noted above with respect to element 1c, a person having ordinary skill in the art would have understood that an insulating layer is non-conductive. Accordingly, the insulating layer (32) of Figure 3A is a second non-conductive layer. (<i>See id.</i> at Fig. 3A.)</p>	<p>The 168 Publication discloses this subject matter. As noted above with respect to element 1a, Fig. 3A of the 427 Publication, incorporated by reference into the 168 Publication, “is [a] perspective view of a stack of materials used in the manufacture of an electrode system of one embodiment. In this embodiment, the composite stack (30) comprises a first insulating layer (32), a first electrode layer (34), a second insulating layer (36), and a second electrode layer (38).” (427 Publication at ¶ 0121.)</p>  <p>(427 Publication at Fig. 3A.)</p> <p>As noted above with respect to element 1c, a person having ordinary skill in the art would have understood that an insulating layer is non-conductive. Accordingly,</p>

Exhibit N

Claim Chart for U.S. Patent No. 10,702,193

Claim 1	Exemplary Disclosure from 518 Publication	Exemplary Disclosure from 168 Publication
	<p>Further, as shown in Figure 3A, the insulating layer (32) (<i>i.e.</i>, “second non-conductive layer”) is located at least in part over the first electrode layer (34) (<i>i.e.</i>, “second conductive layer”). (<i>See</i> 518 Publication at Fig. 3A.) Therefore, the 518 Publication discloses a second non-conductive layer (the insulating layer (32) of Figure 3A) located at least in part over the second conductive layer (the first electrode layer (34) of Figure 3A).</p> <p>Moreover, as also noted above with respect to element 1a, “Figure 5 is a perspective view of an electrode array that is formed by slicing along a plane perpendicular to the longitudinal axis of the spiral roll.” (518 Publication at ¶ 0087.) The electrode array depicted in Figure 5 “includes first insulating layer (52), a working electrode layer (54), a second insulating layer (56), a counter electrode layer (58)” (<i>Id.</i> at ¶ 0136.)</p>	<p>the insulating layer (32) of Figure 3A is a second non-conductive layer. (<i>See id.</i> at Fig. 3A.)</p> <p>Further, as shown in Figure 3A, the insulating layer (32) (<i>i.e.</i>, “second non-conductive layer”) is located at least in part over the first electrode layer (34) (<i>i.e.</i>, “second conductive layer”). (<i>See</i> 427 Publication at Fig. 3A.) Therefore, the 427 Publication discloses a second non-conductive layer (the insulating layer (32) of Figure 3A) located at least in part over the second conductive layer (the first electrode layer (34) of Figure 3A).</p> <p>Moreover, as also noted above with respect to element 1a, “Figure 5 is a perspective view of an electrode array that is formed by slicing along a plane perpendicular to the longitudinal axis of the spiral roll.” (427 Publication at ¶ 0088.) The electrode array depicted in Figure 5 “includes first insulating layer (52), a working electrode layer (54), a second insulating layer (56), a counter electrode layer (58)” (<i>Id.</i> at ¶ 0141.)</p>

Exhibit N

Claim Chart for U.S. Patent No. 10,702,193

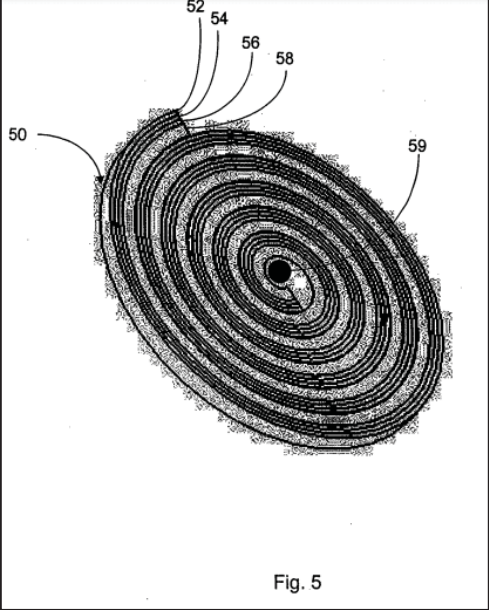
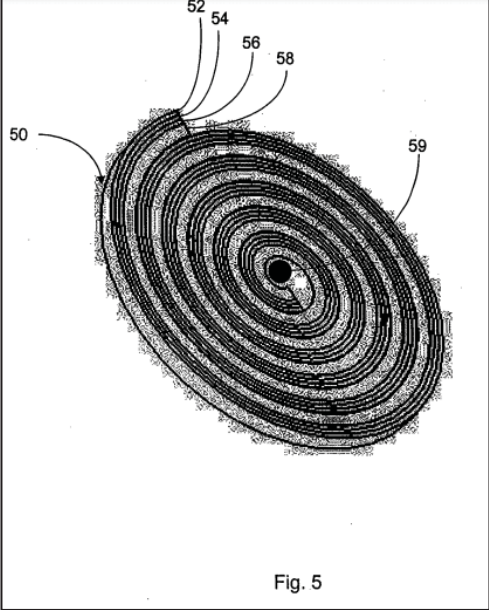
Claim 1	Exemplary Disclosure from 518 Publication	Exemplary Disclosure from 168 Publication
	 <p data-bbox="814 818 869 841">Fig. 5</p> <p data-bbox="430 881 772 914">(518 Publication at Fig. 5.)</p> <p data-bbox="430 935 1146 1114">As explained above, a person having ordinary skill in the art would have understood that an insulating layer is non-conductive. (<i>See, e.g.</i>, 518 Publication at ¶ 0125.) Accordingly, the insulating layer (52) of Figure 5 is a second non-conductive layer. (<i>See id.</i> at Fig. 5.)</p> <p data-bbox="430 1135 1146 1383">Further, as shown in Figure 5, the insulating layer (52) (<i>i.e.</i>, “second non-conductive layer”) is located at least in part over the first electrode layer (54) (<i>i.e.</i>, “second conductive layer”). (<i>See</i> 518 Publication at Fig. 5.) Accordingly, the 518 Publication discloses a second non-conductive layer (the insulating layer (52) of Figure 5) located at least in part over the second</p>	 <p data-bbox="1560 818 1614 841">Fig. 5</p> <p data-bbox="1173 881 1516 914">(427 Publication at Fig. 5.)</p> <p data-bbox="1173 935 1890 1114">As explained above, a person having ordinary skill in the art would have understood that an insulating layer is non-conductive. (<i>See, e.g.</i>, 427 Publication at ¶ 0129.) Accordingly, the insulating layer (52) of Figure 5 is a second non-conductive layer. (<i>See id.</i> at Fig. 5.)</p> <p data-bbox="1173 1135 1890 1383">Further, as shown in Figure 5, the insulating layer (52) (<i>i.e.</i>, “second non-conductive layer”) is located at least in part over the first electrode layer (54) (<i>i.e.</i>, “second conductive layer”). (<i>See</i> 427 Publication at Fig. 5.) Accordingly, the 427 Publication discloses a second non-conductive layer (the insulating layer (52) of Figure 5) located at least in part over the second</p>

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Claim Chart for U.S. Patent No. 10,702,193

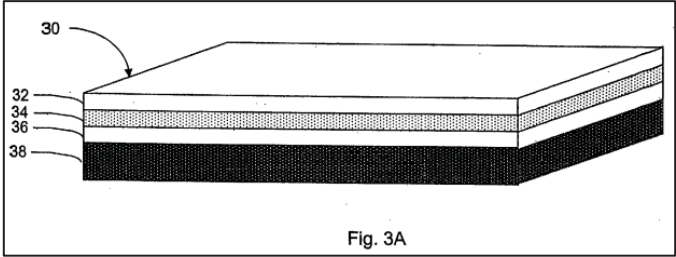
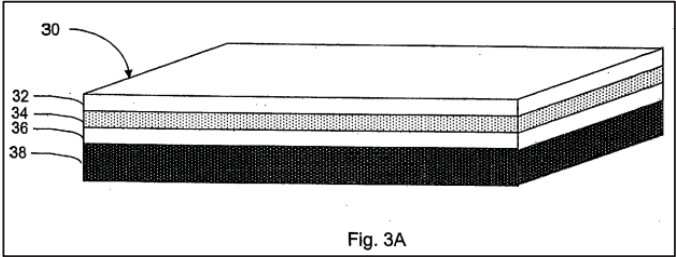
Claim 1	Exemplary Disclosure from 518 Publication	Exemplary Disclosure from 168 Publication
	<p>conductive layer (the of working electrode layer (54) Figure 5).</p> <p>Therefore, the 518 Publication discloses a second non-conductive layer located at least in part over the second conductive layer.</p>	<p>conductive layer (the of working electrode layer (54) Figure 5).</p> <p>Therefore, through incorporation by reference of the 427 Publication, the 168 Publication discloses a second non-conductive layer located at least in part over the second conductive layer.</p>
<p>[1f] a third conductive layer associated with a third electrode, wherein the third conductive layer is located at least in part over the second non-conductive layer; and</p>	<p>The 518 Publication discloses this subject matter. As noted above with respect to element 1a, “Fig. 3A is [a] perspective view of a stack of materials used in the manufacture of an electrode system of one embodiment. In this embodiment, the composite stack (30) comprises a first insulating layer (32), a first electrode layer (34), a second insulating layer (36), and a second electrode layer (38).” (518 Publication at ¶ 0117.)</p>  <p>(518 Publication at Fig. 3A.)</p> <p>Further, the 518 Publication discloses that “the composite stack can include . . . any combination of one or more working electrode layers, counter electrode layers, and/or reference electrode layers.” (518 Publication at ¶ 0118.) For example, the electrode array can comprise “at least a working electrode and a</p>	<p>The 168 Publication discloses this subject matter. As noted above with respect to element 1a, Fig. 3A of the 427 Publication, incorporated by reference into the 168 Publication, “is [a] perspective view of a stack of materials used in the manufacture of an electrode system of one embodiment. In this embodiment, the composite stack (30) comprises a first insulating layer (32), a first electrode layer (34), a second insulating layer (36), and a second electrode layer (38).” (427 Publication at ¶ 0121.)</p>  <p>(427 Publication at Fig. 3A.)</p> <p>Further, the 427 Publication discloses that “the composite stack can include . . . any combination of one or more working electrode layers, counter electrode layers, and/or reference electrode layers.” (427</p>

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Claim Chart for U.S. Patent No. 10,702,193

Claim 1	Exemplary Disclosure from 518 Publication	Exemplary Disclosure from 168 Publication
	<p>reference electrode with an insulating material disposed therebetween” and “additional electrodes can be included within the electrode array, for example, a three-electrode system (working, reference, and counter electrodes)” (<i>Id.</i> at ¶ 0105.) As such, a person having ordinary skill in the art would have understood from the 518 Publication that the composite stack of Figure 3A teaches a three-electrode system, that includes an additional, third electrode layer.</p> <p>The 518 Publication further teaches that “[i]nsulating material can be layered between the electrode layers.” (518 Publication at ¶ 0119.) Thus, a person having ordinary skill in the art would have understood that the third electrode layer would be deposited on top of the insulating layer (32) (<i>i.e.</i>, “the second conductive layer”) as expressly taught in connection with FIG. 3A.</p> <p>Moreover, as noted above with respect to elements 1b and 1d, the 518 Publication discloses that the electrode layers “can comprise any suitable metal or conductive polymer electrode material” (518 Publication at ¶ 0125.) Accordingly, the third electrode layer added to the composite stack of Figure 3A would be the third conductive layer associated with a third electrode.</p> <p>Further, as also noted above with respect to element 1a, “Figure 5 is a perspective view of an electrode array that is formed by slicing along a plane perpendicular to the longitudinal axis of the spiral roll [of Figure 4].” (518 Publication at ¶¶ 0087, 0135.) The electrode array depicted in Figure 5 “includes first insulating layer (52), a working electrode layer (54), a second insulating layer (56), a counter electrode layer (58)” (<i>Id.</i> at ¶ 0136.)</p>	<p>Publication at ¶ 0122.) For example, the electrode array can comprise “at least a working electrode and a reference electrode with an insulating material disposed therebetween” and “additional electrodes can be included within the electrode array, for example, a three-electrode system (working, reference, and counter electrodes)” (<i>Id.</i> at ¶ 0108.) As such, a person having ordinary skill in the art would have understood from the 427 Publication that the composite stack of Figure 3A teaches a three-electrode system, that includes an additional third electrode layer.</p> <p>The 427 Publication further teaches that “[i]nsulating material can be layered between the electrode layers.” (427 Publication at ¶ 0123.) A person having ordinary skill in the art would have understood that the third electrode layer would be deposited on top of the insulating layer (32) (<i>i.e.</i>, “the second conductive layer”) as expressly taught in connection with FIG. 3A.</p> <p>Moreover, as noted above with respect to elements 1b and 1d, the 427 Publication discloses that the electrode layers “can comprise any suitable metal or conductive polymer electrode material” (427 Publication at ¶ 0129.) Accordingly, the third electrode layer added to the composite stack of Figure 3A would be the third conductive layer associated with a third electrode.</p> <p>Further, as also noted above with respect to element 1a, “Figure 5 is a perspective view of an electrode array that is formed by slicing along a plane perpendicular to the longitudinal axis of the spiral roll [of Figure 4].” (427 Publication at ¶¶ 0088, 0140.) The electrode array depicted in Figure 5 “includes first insulating layer (52),</p>

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Claim Chart for U.S. Patent No. 10,702,193

Claim 1	Exemplary Disclosure from 518 Publication	Exemplary Disclosure from 168 Publication
	<p>In Figure 5, the third electrode (central reference electrode (59)) has been “optionally . . . incorporated into the center of the rolled composite stack . . .” (<i>Id.</i> at ¶ 0132.) Alternatively, the 518 Publication teaches that the reference electrode can be incorporated as a “reference electrode layer.” (<i>Id.</i>) Moreover, the “composition and configuration of the electrode array (50) [illustrated in Figure 5] can depend on the chosen composition and configuration of materials that formed the composite stack and/or spiral roll (4), such as described in more detail with reference to Figs. 3 and 4.” (<i>Id.</i> at ¶ 0136.) Accordingly, a person having ordinary skill in the art would have understood from the 518 Publication that the electrode array of Figure 5 teaches a three-electrode system where the third electrode is included as a third electrode layer that is placed above insulating layer (52), as taught with reference to the composite stack of Figure 3.</p> <p>Therefore, the 518 Publication discloses a third conductive layer associated with a third electrode (the third electrode layer), wherein the third conductive layer is located at least in part over the second non-conductive layer (the insulating layer (32) of Figure 3A and the insulating layer (52) of Figure 5).</p>	<p>a working electrode layer (54), a second insulating layer (56), a counter electrode layer (58)” (<i>Id.</i> at ¶ 0141.) In Figure 5, the third electrode (central reference electrode (59)) has been “optionally . . . incorporated into the center of the rolled composite stack . . .” (<i>Id.</i> at ¶ 0136.) Alternatively, the 427 Publication teaches that the reference electrode can be incorporated as a “reference electrode layer.” (<i>Id.</i>) Moreover, the “composition and configuration of the electrode array (50) [illustrated in Figure 5] can depend on the chosen composition and configuration of materials that formed the composite stack and/or spiral roll (4), such as described in more detail with reference to Figs. 3 and 4.” (<i>Id.</i> at ¶ 0141.) Accordingly, a person having ordinary skill in the art would have understood from the 427 Publication that the electrode array of Figure 5 teaches a three-electrode system where the third electrode is included as a third electrode layer that is placed above insulating layer (52), as taught with reference to the composite stack of Figure 3.</p> <p>Therefore, through incorporation by reference of the 427 Publication, the 168 Publication discloses a third conductive layer associated with a third electrode (the third electrode layer), wherein the third conductive layer is located at least in part over the second non-conductive layer (the insulating layer (32) of Figure 3A and the insulating layer (52) of Figure 5).</p>
[1g] a membrane located over at	The 518 Publication discloses this subject matter. The 518 Publication teaches that the “sensing region” is “the region of a monitoring device responsible for the	The 168 Publication discloses this subject matter. The 168 Publication discloses “a glucose-measuring working electrode 16” that is “disposed beneath an

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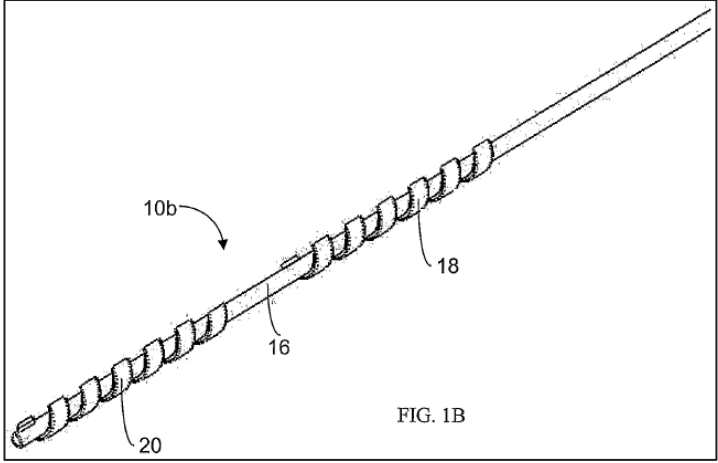
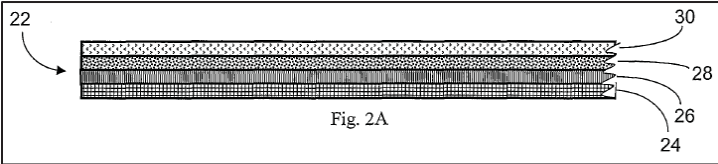
Claim 1	Exemplary Disclosure from 518 Publication	Exemplary Disclosure from 168 Publication
<p>least a portion of a working electrode;</p>	<p>detection of a particular analyte.” (518 Publication at ¶ 0099.) “The sensing region generally comprises a non-conductive body, a working electrode (anode), a reference electrode (optional), and/or a counter electrode (cathode) passing through and secured within the body forming electrochemically reactive surfaces on the body and an electronic connective means at another location on the body, and a multi-domain membrane affixed to the body and covering the electrochemically reactive surface.” (<i>Id.</i>) A person having ordinary skill in the art would have understood that a membrane affixed to the body and covering the electroactive surfaces formed by electrodes, including a working electrode, is a membrane located over at least a portion of a working electrode.</p> <p>The 518 Publication also discloses that “the electrode array is operably connected to the sensor electronics (Fig. 2) and includes electroactive surfaces, which are covered by a membrane system (18). The membrane system (18) is disposed over the electroactive surfaces of the electrode array (16) . . .” (518 Publication at ¶ 0104.)</p>	<p>active enzymatic portion of a membrane system . . .” (168 Publication at ¶ 0074.) Accordingly, the membrane would be located over at least a portion of a working electrode. (<i>Id.</i> at ¶ 0074.)</p> <div data-bbox="1178 410 1892 870">  <p>FIG. 1B</p> </div> <p>(168 Publication at Fig. 1B.)</p> <p>Moreover, the 168 Publication also discloses “a membrane system (see Fig. 2A) is deposited over the electroactive surfaces of the sensor 10a . . .” (168 Publication at ¶ 0071.)</p> <div data-bbox="1178 1101 1892 1263">  <p>Fig. 2A</p> </div> <p>(168 Publication at Fig. 2A.)</p> <p>For example, “[i]n the illustrated embodiments of Figs. 3A and 3B, the membrane system 22 is positioned at</p>

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Claim Chart for U.S. Patent No. 10,702,193

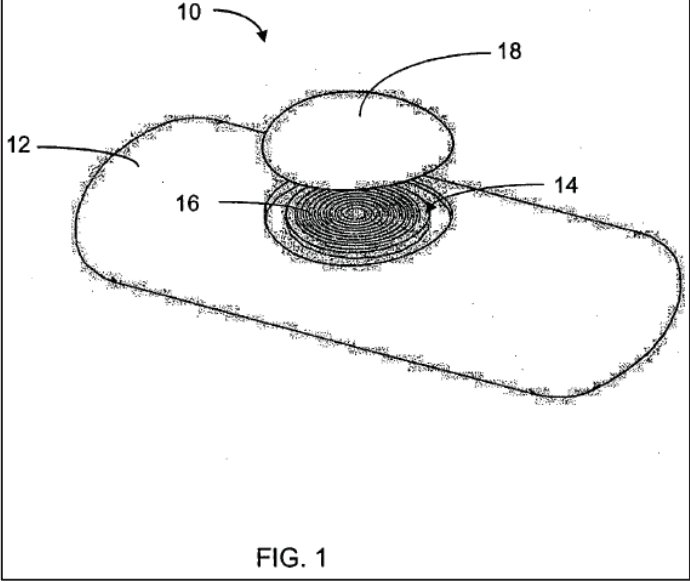
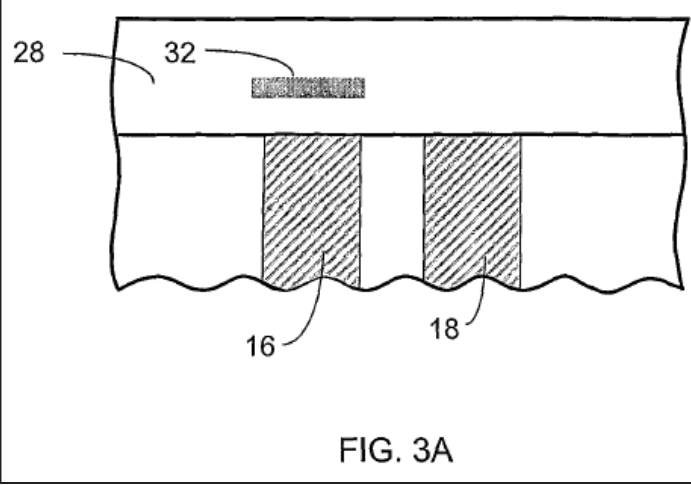
Claim 1	Exemplary Disclosure from 518 Publication	Exemplary Disclosure from 168 Publication
	 <p>FIG. 1</p> <p>(518 Publication at Fig. 1.)</p> <p>The 518 Publication further discloses that “the electrode array, which is located on or within the sensing region (14), is comprised of at least a working electrode and a reference electrode with an insulating material disposed therebetween” and that “additional electrodes can be included within the electrode array, for example, a three-electrode system (working, reference, and counter electrodes). (518 Publication at ¶ 0105.) A person having ordinary skill in the art would have understood that a membrane covering the electroactive surfaces of an electrode array comprised of at least a working electrode is a membrane located over at least a portion of a working electrode.</p>	<p>least over the glucose-measuring working electrode 16 and the optional auxiliary working electrode 18” (168 Publication at ¶ 0096.)</p>  <p>FIG. 3A</p> <p>(168 Publication at Fig. 3A.)</p>

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Claim Chart for U.S. Patent No. 10,702,193

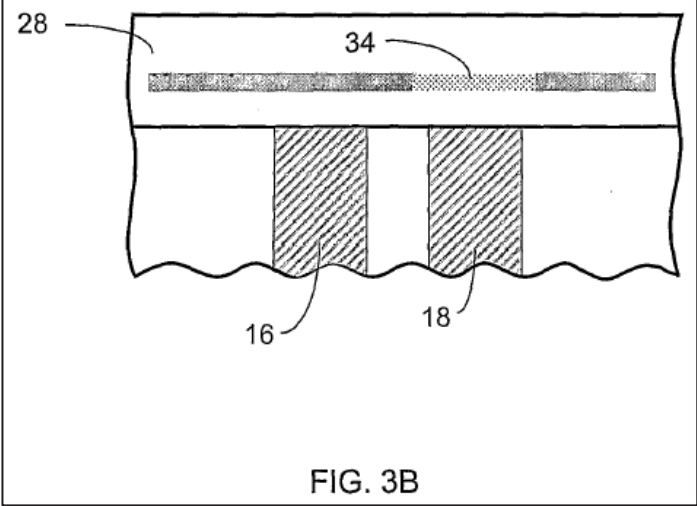
Claim 1	Exemplary Disclosure from 518 Publication	Exemplary Disclosure from 168 Publication
	<p>Therefore, the 518 Publication discloses a membrane located over at least a portion of a working electrode.</p>	<div data-bbox="1188 250 1881 753">  </div> <p>(168 Publication at 3B.)</p> <p>As another example, the 168 Publication states “[r]eference is now made to Fig. 3A, which is a cross-sectional exploded schematic view of the sensing region in one embodiment wherein an active enzyme 32 of the enzyme domain is positioned only over the glucose-measuring working electrode 16. In this embodiment, the membrane system is formed such that the glucose oxidase 32 only exists above the glucose-measuring working electrode 16.” (168 Publication ¶ 0097.)</p> <p>The 168 Publication also teaches that the “sensing region” is “the region of a monitoring device responsible for the detection of a particular analyte.” (168 Publication at ¶ 0031.) “[T]he sensing region generally comprises a non-conductive body, at least one electrode, a reference electrode and a optionally a counter electrode passing through and secured within</p>

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Claim Chart for U.S. Patent No. 10,702,193

Claim 1	Exemplary Disclosure from 518 Publication	Exemplary Disclosure from 168 Publication
		<p>the body forming an electrochemically reactive surface at one location on the body and an electronic connection at another location on the body, and a membrane system affixed to the body and covering the electrochemically reactive surface.” (<i>Id.</i> at ¶ 0031.)</p> <p>The 427 Publication, incorporated by reference into the 168 Publication, teaches that “the electrode array is operably connected to the sensor electronics (Fig. 2) and includes electroactive surfaces, which are covered by a membrane system (18). The membrane system (18) is disposed over the electroactive surfaces of the electrode array (16)” (427 Publication at ¶ 0107.)</p> <div data-bbox="1178 716 1885 1320"> <p style="text-align: center;">FIG. 1</p> </div> <p>(427 Publication at Fig. 1.)</p>

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Claim Chart for U.S. Patent No. 10,702,193

Claim 1	Exemplary Disclosure from 518 Publication	Exemplary Disclosure from 168 Publication
		<p>The 427 Publication further teaches that “the electrode array, which is located on or within the sensing region (14), is comprised of at least a working electrode and a reference electrode with an insulating material disposed therebetween” and that “additional electrodes can be included within the electrode array, for example, a three-electrode system (working, reference, and counter electrodes)” (427 Publication at ¶ 0108.)</p> <p>Therefore, through incorporation by reference of the 427 Publication, the 168 Publication discloses a membrane located over at least a portion of a working electrode.</p>
<p>[1h] wherein at least one of the first electrode, the second electrode, or the third electrode is the working electrode, and</p>	<p>The 518 Publication discloses this subject matter. The 518 Publication discloses that “the composite stack can include . . . any combination of one or more working electrode layers, counter electrode layers, and/or reference electrode layers.” (518 Publication at ¶ 0118.) For example, “the electrode array, which is located on or within the sensing region (14), is comprised of at least a working electrode and a reference electrode with an insulating material disposed therebetween” and “additional electrodes can be included within the electrode array, for example, a three-electrode system (working, reference, and counter electrodes)” (<i>Id.</i> at ¶ 0105.) For example, the 518 Publication teaches a three-electrode array “wherein the first electrode material includes a working electrode, wherein the second electrode material includes a counter electrode, and wherein the third electrode material includes a reference electrode.” (<i>Id.</i> at ¶ 0024;</p>	<p>The 168 Publication discloses this subject matter. The 168 Publication discloses “a transcutaneous analyte sensor” that “includes three electrodes: a glucose-measuring working electrode 16, an optional auxiliary working electrode 18, and at least one additional electrode 20, which may function as a counter and/or reference electrode” (168 Publication at ¶ 0074.) Therefore, the 168 Publication discloses that at least one of the first electrode, the second electrode, or the third electrode is the working electrode.</p> <p>The 427 Publication, incorporated by reference into the 168 Publication, discloses that “the composite stack can include . . . any combination of one or more working electrode layers, counter electrode layers, and/or reference electrode layers.” (427 Publication at ¶ 0122.) For example, “the electrode array, which is located on or within the sensing region (14), is</p>

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Claim Chart for U.S. Patent No. 10,702,193

Claim 1	Exemplary Disclosure from 518 Publication	Exemplary Disclosure from 168 Publication
	<p><i>see also</i> ¶¶ 0025, 0027, 0058, 0064 (additional three-electrode electrode arrays wherein at least one of the three electrodes is a working electrode).)</p> <p>Therefore, the 518 Publication discloses at least one of the first electrode, the second electrode, or the third electrode is the working electrode.</p>	<p>comprised of at least a working electrode and a reference electrode with an insulating material disposed therebetween” and “additional electrodes can be included within the electrode array, for example, a three-electrode system (working, reference, and counter electrodes)” (<i>Id.</i> at ¶ 0108.) For example, the 427 Publication teaches a three-electrode electrode array “wherein the first electrode material includes a working electrode, wherein the second electrode material includes a working electrode, and wherein the third electrode material includes a reference electrode.” (<i>Id.</i> at ¶ 0025.)</p> <p>Therefore, through incorporation by reference of the 427 Publication, the 168 Publication discloses at least one of the first electrode, the second electrode, or the third electrode is the working electrode.</p>
[1i] wherein the working electrode is configured to measure a signal indicative of a glucose concentration.	<p>The 518 Publication discloses this subject matter. The 518 Publication discloses “an implantable glucose sensor (10) that utilizes amperometric electrochemical sensor technology to measure glucose.” (518 Publication at ¶ 0103.) The 518 Publication also discloses that, “[i]n a glucose oxidase-based glucose sensor, the species measured at the working electrode is H₂O₂.” (<i>Id.</i> at ¶ 0106.) “The change in H₂O₂ can be monitored to determine glucose concentration” (<i>Id.</i> at ¶ 0107.) Therefore, the 518 Publication discloses that the working electrode is configured to measure a signal indicative of a glucose concentration.</p>	<p>The 168 Publication discloses this subject matter. The 168 Publication discloses “a transcutaneous analyte sensor” that “includes three electrodes” one of which is “a glucose-measuring working electrode 16.” (168 Publication at ¶ 0074.) “The glucose-measuring working electrode 16 is configured and arranged to measure the concentration of glucose.” (<i>Id.</i> at ¶ 0076.) The sensor includes the ability to measure “a signal associated with glucose...wherein the [] signal is measured at the glucose-measuring working electrode.” (<i>Id.</i> at ¶ 0074.) Therefore, the 168 Publication discloses that the working electrode is configured to measure a signal indicative of a glucose concentration.</p>

Exhibit N

Claim Chart for U.S. Patent No. 10,702,193

Claim 1	Exemplary Disclosure from 518 Publication	Exemplary Disclosure from 168 Publication
	<p>As another example, the 518 Publication states “[i]n one embodiment, the electrochemical measuring circuit can be a potentiostat,” which “applies a constant potential to the working and reference electrodes to determine a current value.” (518 Publication at ¶ 0110.) “The current that is produced at the working electrode is proportional to the diffusional flux of H_2O_2. Accordingly, a raw signal can be produced that is representative of the concentration of glucose in the user’s body, and therefore can be utilized to estimate a meaningful glucose value, such as described elsewhere herein.” (<i>Id.</i>)</p> <p>Moreover, the 518 Publication further discloses that “one or more electrodes can be used to detect the amount of analyte in a sample and convert that information into a signal; the signal can then be transmitted to a circuit. In this case, the electrode is ‘operably linked’ to the electronic circuitry.” (518 Publication at ¶ 0096.) And in another example, “a working electrode measures hydrogen peroxide produced by the enzyme catalyzed reaction of the analyte being detected reacts creating an electric current (for example, detection of glucose analyte utilizing glucose oxidase produces H_2O_2 as a byproduct, H_2O_2 reacts with the surface of the working electrode producing two protons ($2H^+$), two electrons ($2e^-$) and one molecule of oxygen (O_2) which produces the electronic current being detected). In the case of the counter electrode, a reducible species, for example, O_2 is reduced at the electrode surface in order to balance</p>	<p>The 427 Publication, incorporated by reference into the 168 Publication, discloses “an implantable glucose sensor (10) that utilizes amperometric electrochemical sensor technology to measure glucose.” (427 Publication at ¶ 0106.) The 427 Publication also discloses that, “[i]n a glucose oxidase-based glucose sensor, the species measured at the working electrode is H_2O_2.” (<i>Id.</i> at ¶ 0109.) “The change in H_2O_2 can be monitored to determine glucose concentration” (<i>Id.</i> at ¶ 0110.)</p> <p>As another example, the 427 Publication states “[i]n one embodiment, the electrochemical measuring circuit can be a potentiostat,” which “applies a constant potential to the working and reference electrodes to determine a current value.” (427 Publication at ¶ 0113.) “The current that is produced at the working electrode is proportional to the diffusional flux of H_2O_2. Accordingly, a raw signal can be produced that is representative of the concentration of glucose in the user’s body, and therefore can be utilized to estimate a meaningful glucose value, such as described elsewhere herein.” (<i>Id.</i>)</p> <p>Moreover, the 427 Publication further discloses that “one or more electrodes can be used to detect the amount of analyte in a sample and convert that information into a signal; the signal can then be transmitted to a circuit. In this case, the electrode is ‘operably linked’ to the electronic circuitry.” (427 Publication at ¶ 0098.) And in another example, “a working electrode measures hydrogen peroxide produced by the enzyme catalyzed reaction of the</p>

Exhibit N**Claim Chart for U.S. Patent No. 10,702,193**

Claim 1	Exemplary Disclosure from 518 Publication	Exemplary Disclosure from 168 Publication
	<p>the current being generated by the working electrode.” (<i>Id.</i> at ¶ 0098.)</p> <p>Therefore, the 518 Publication discloses the working electrode is configured to measure a signal indicative of a glucose concentration.</p>	<p>analyte being detected reacts creating an electric current (for example, detection of glucose analyte utilizing glucose oxidase produces H_2O_2 as a byproduct, H_2O_2 reacts with the surface of the working electrode producing two protons ($2H^+$), two electrons ($2e^-$) and one molecule of oxygen (O_2) which produces the electronic current being detected). In the case of the counter electrode, a reducible species, for example, O_2 is reduced at the electrode surface in order to balance the current being generated by the working electrode.” (<i>Id.</i> at ¶ 0100.)</p> <p>Therefore, through incorporation by reference of the 427 Publication, the 168 Publication discloses the working electrode is configured to measure a signal indicative of a glucose concentration.</p>

EXHIBIT 10

EXHIBIT O

Exhibit O

Claim Chart for U.S. Patent No. 10,980,452

Asserted Patent:

- U.S. Pat. No. 10,980,452 (“452 Patent”) (Ex. P)
 - Filing date: November 3, 2020
 - Earliest claimed priority date: February 22, 2006

Patent or Patent Application Captured in Subsection (a) of Paragraph A.13:

- U.S. Provisional Appl. No. 60/614,683 (“683 Provisional”) (Ex. G)
 - Filing date: September 30, 2004

Exhibit O

Claim Chart for U.S. Patent No. 10,980,452

Claim 19	Exemplary Disclosure
<p>[19Pre] A system for measuring a glucose concentration in a host, the system comprising:</p>	<p>To the extent the preamble is limiting, the 683 Provisional discloses this subject matter. The 683 Provisional relates generally to “systems and methods for measuring an analyte in a host.” (683 Provisional at G-004 (¶ 0001).) More particularly the 683 Provisional relates to “systems and methods for transcutaneous measurement of glucose in a host.” (<i>Id.</i>)</p> <p>The 683 Provisional therefore discloses a system for measuring a glucose concentration in a host.</p>
<p>[19a] a transcutaneous glucose sensor;</p>	<p>The 683 Provisional discloses this subject matter. The 683 Provisional states “a transcutaneous glucose sensor for measuring glucose concentration in a host is provided.” (683 Provisional at G-012 (¶ 0063).)</p> <p>Figure 4 of the 683 Provisional, provided below, includes a depiction of a transcutaneous glucose sensor as a component of an assembly. (683 Provisional at G-013 (¶ 0073).) Figure 4 illustrates “sensor 32 [including] a distal portion 42, also referred to as the in vivo portion, adapted for insertion under the host's skin, and a proximal portion 40, also referred to as an ex vivo portion, adapted to remain above the host's skin after sensor insertion and to operably connect to the electronics unit 16”, and indicates that “[a]lthough the illustrated electrode configuration and associated text describe one preferred method of forming a transcutaneous sensor, a variety of known transcutaneous sensor configurations can be applied to the transcutaneous analyte sensor system of the preferred embodiments” (<i>Id.</i> at G-024 (¶ 0122).)</p>

Exhibit O

Claim Chart for U.S. Patent No. 10,980,452

Claim 19	Exemplary Disclosure
	<div data-bbox="596 350 1003 477" data-label="Text"> <p>transcutaneous glucose sensor (sensor 32 having distal (in vivo) portion 42)</p> </div> <div data-bbox="1050 250 1740 829" data-label="Image"> </div> <div data-bbox="445 865 1064 901" data-label="Text"> <p>(683 Provisional at G-053 (Fig. 4) (annotated).)</p> </div> <div data-bbox="445 917 1388 953" data-label="Text"> <p>Therefore, the 683 Provisional discloses a transcutaneous glucose sensor.</p> </div>
<p>[19b] sensor electronics configured to operably connect to the transcutaneous glucose sensor;</p>	<p>The 683 Provisional discloses this subject matter. The 683 Provisional states “the sensor 32 includes a distal portion 42, also referred to as the in vivo portion, adapted for insertion under the host’s skin, and a proximal portion 40, also referred to as an ex vivo portion, adapted to remain above the host’s skin after sensor insertion and to operably connect to the electronics unit 16.” (683 Provisional at G-024 (¶ 0122); <i>see also, id.</i> at G-021 (¶ 0113) (“The sensor 32 is configured to extend out of the mounting unit and into the host’s skin at its distal portion, and to operably connect with the electronics unit 16 at its proximal portion to enable measurement of the analyte.”).)</p> <p>Figure 3 of the 683 Provisional, provided below, illustrates sensor electronics (electronics unit 16) configured to operably connect to the transcutaneous glucose sensor (sensor 32).</p>

Exhibit O

Claim Chart for U.S. Patent No. 10,980,452

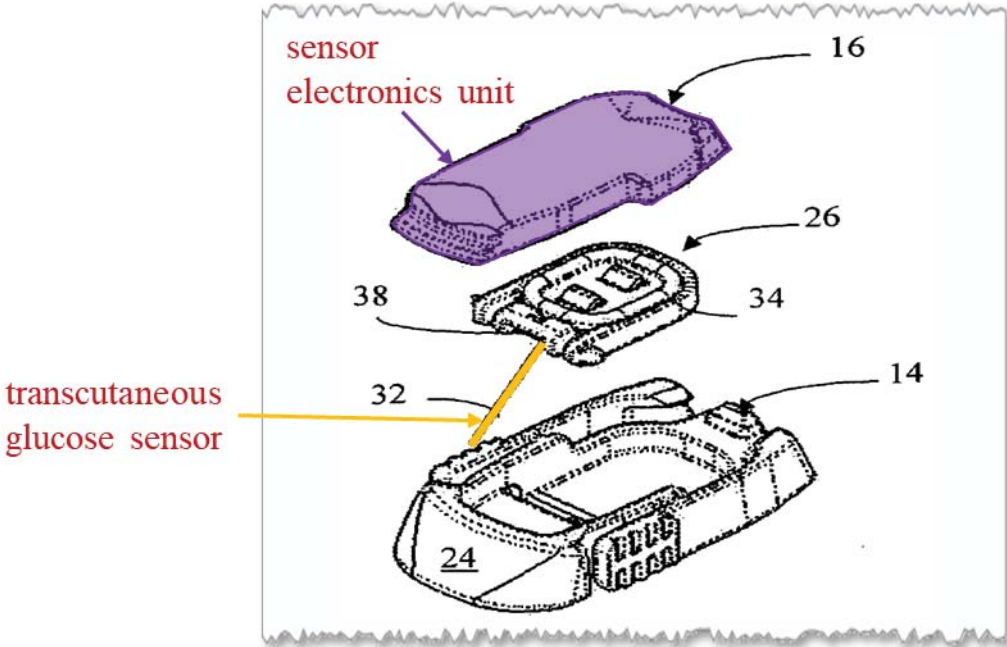
Claim 19	Exemplary Disclosure
	 <p>(683 Provisional at G-052 (Fig. 3) (annotated).)</p> <p>Therefore, the 683 Provisional discloses sensor electronics configured to operably connect to the transcutaneous glucose sensor.</p>
<p>[19c] an electrical contact configured to operably connect the transcutaneous glucose sensor to</p>	<p>The 683 Provisional discloses this subject matter. The 683 Provisional states that “the mounting unit comprises a contact subassembly configured to hold at least one contact therein for providing electrical connection between the sensor and the electronics unit.” (683 Provisional at G-023 (¶ 0019); <i>see also, id.</i> at G-021 (¶ 0112) (“The mounting unit 14 includes a base 24 adapted for mounting on the skin of a host, a sensor 32 adapted for transdermal insertion through the skin of a host, and one or more contacts 28 configured to provide secure electrical contact between sensor 32 and the electronics unit 16.”).)</p>

Exhibit O

Claim Chart for U.S. Patent No. 10,980,452

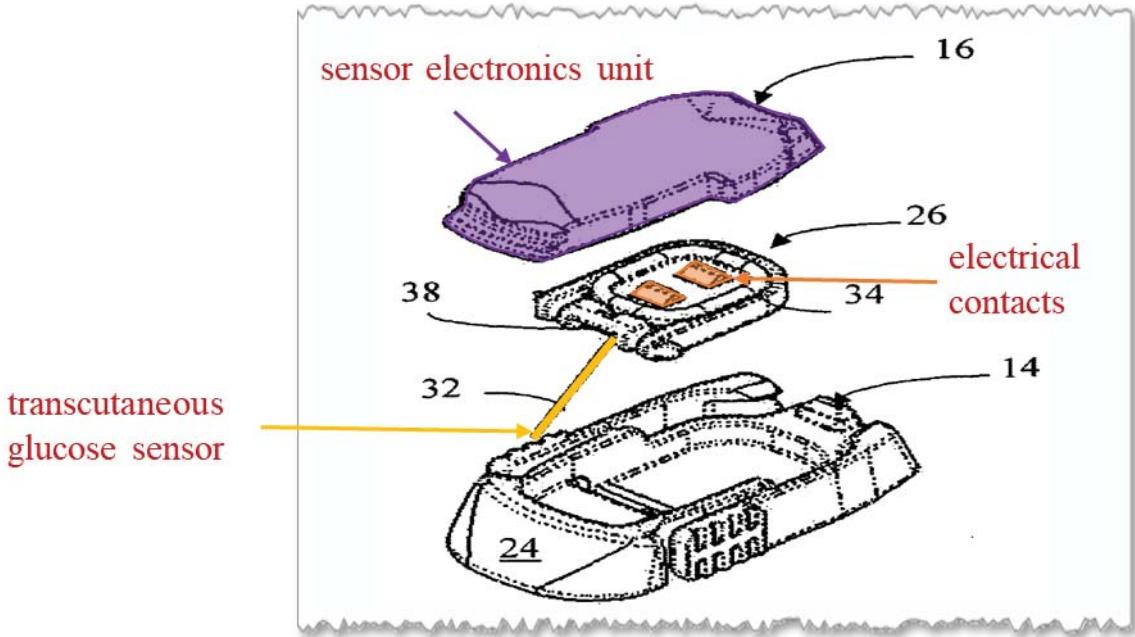
Claim 19	Exemplary Disclosure
the sensor electronics;	<p>Figures 3 and 4 of the 683 Provisional, provided below, illustrate electrical contacts (contacts 28 shown in Fig 4) configured to operably connect the transcutaneous glucose sensor (proximal portion 40 of sensor 32) to the sensor electronics (electronics unit 16 shown in Fig. 3).</p>  <p>The diagram illustrates a transcutaneous glucose sensor system. At the top, a purple rectangular block represents the 'sensor electronics unit' (16). Below it, a component (26) contains 'electrical contacts' (34). To the left, a yellow arrow points from the text 'transcutaneous glucose sensor' to a device (32). The device (32) has a proximal portion (40) with electrical contacts (38) and a distal portion (24). A yellow arrow points from the proximal portion (40) of the sensor (32) towards the electrical contacts (34) on component (26). Component (14) is also shown at the bottom right.</p> <p>(683 Provisional at G-052 (Fig. 3) (annotated).)</p>

Exhibit O

Claim Chart for U.S. Patent No. 10,980,452

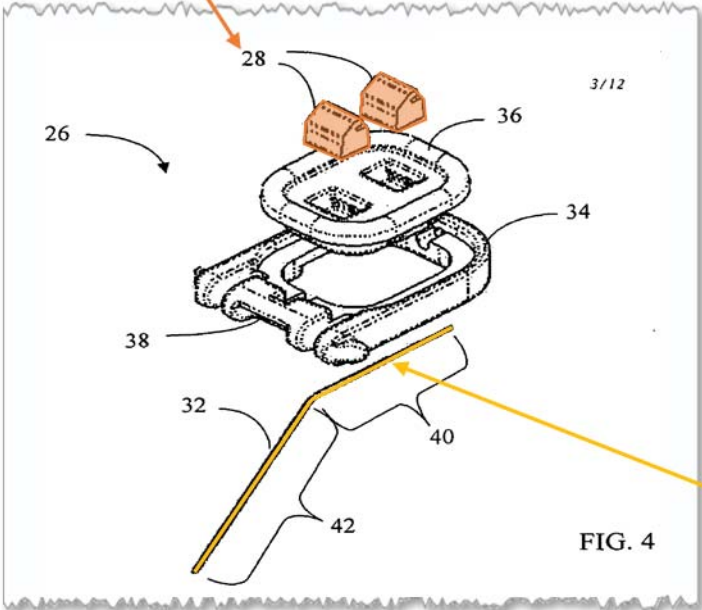
Claim 19	Exemplary Disclosure
	<p>electrical contacts (contacts 28)</p>  <p>transcutaneous glucose sensor (sensor 32 having proximal (ex vivo) portion 40 adapted to connect to electronics unit 16)</p> <p>(683 Provisional at G-053 (Fig. 4) (annotated).)</p> <p>Therefore, the 683 Provisional discloses an electrical contact configured to operably connect the transcutaneous glucose sensor to the sensor electronics.</p>
<p>[19d] a sealing member comprising a sealing member upper portion and a sealing</p>	<p>The 683 Provisional discloses this subject matter. The 683 Provisional states “[a] seal 36, also referred to as a seal ring, fits within the contact holder 34 and provides a gas-tight seal configured to protect the contacts 28 from outside moisture that can cause corrosion of the contacts and their conductive properties.” (683 Provisional at G-023 (¶ 0118); <i>see also, id.</i> at G-009 (¶ 0041) (“the contact subassembly is configured to form a seal with the electronics unit when mated therein.”).)</p>

Exhibit O

Claim Chart for U.S. Patent No. 10,980,452

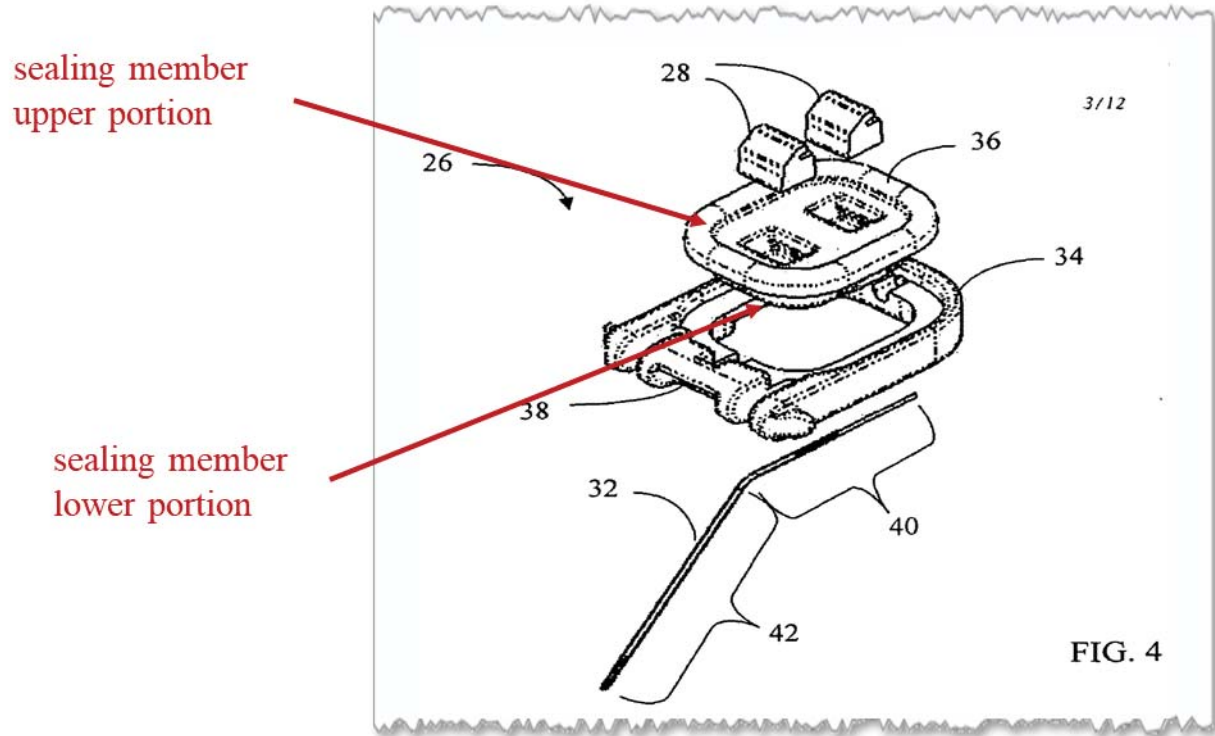
Claim 19	Exemplary Disclosure
member lower portion,	<p>Additionally, Figures 3, 7D and 10B of the 683 Provisional, provided below, also illustrate a sealing member comprising a sealing member upper portion and a sealing member lower portion.</p>  <p>(683 Provisional at G-053 (Fig. 4) (annotated).)</p>

Exhibit O

Claim Chart for U.S. Patent No. 10,980,452

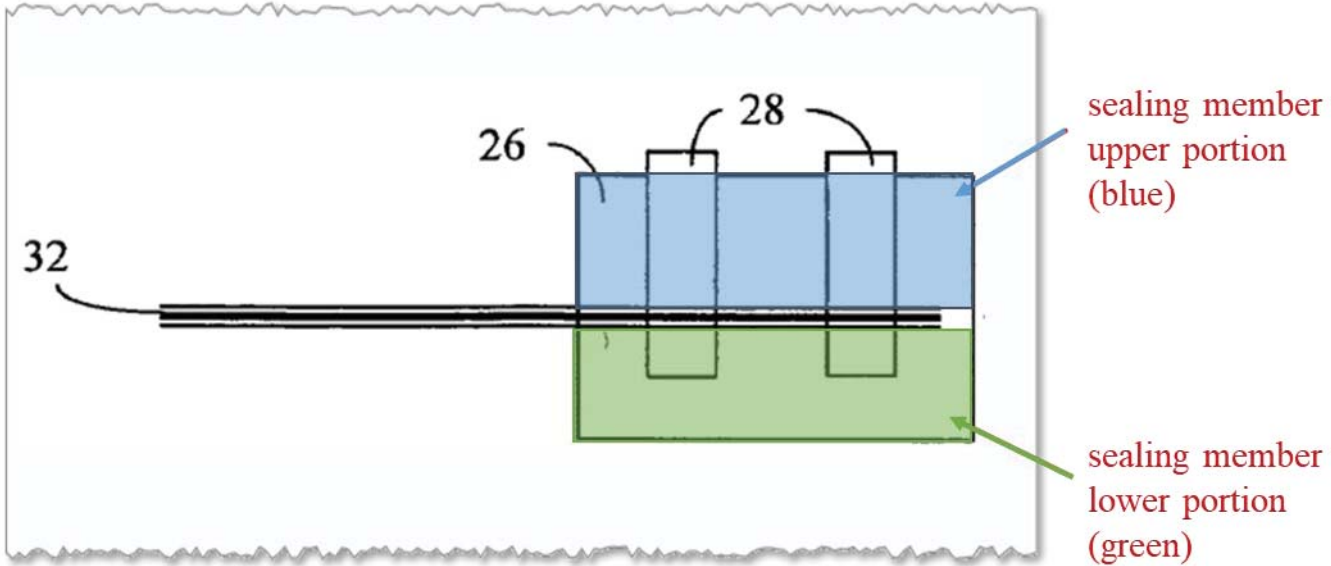
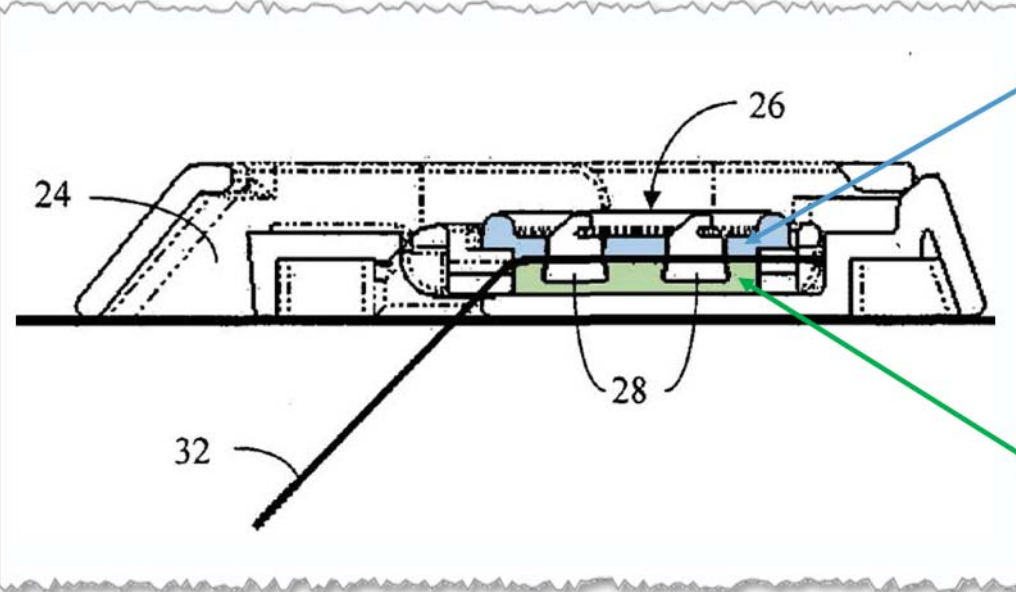
Claim 19	Exemplary Disclosure
	 <p>The diagram shows a cross-sectional view of a device. A horizontal line, labeled 32, passes through a rectangular block. The block is divided into two horizontal sections: a top section colored blue and a bottom section colored green. The blue section is labeled 'sealing member upper portion (blue)' with a blue arrow pointing to it. The green section is labeled 'sealing member lower portion (green)' with a green arrow pointing to it. Two vertical rectangular features, labeled 26 and 28, are positioned on the top surface of the blue section. The entire assembly is shown within a light blue rectangular frame with a wavy, torn-edge border.</p> <p>(683 Provisional at G-057 (Fig. 7D) (truncated and annotated).)</p>

Exhibit O

Claim Chart for U.S. Patent No. 10,980,452

Claim 19	Exemplary Disclosure
	 <p>(683 Provisional at G-060 (Fig. 10B) (annotated).)</p> <p>Therefore, the 683 Provisional discloses a sealing member comprising a sealing member upper portion and a sealing member lower portion.</p>
<p>[19e] wherein the sealing member at least partially surrounds the electrical contact and at least a</p>	<p>The 683 Provisional discloses this subject matter. The 683 Provisional states “[c]ontacts 28 fit within the seal 36 and provide for electrical connection between the sensor 32 and the electronics unit 16.” (683 Provisional at G-023 (¶ 0119); <i>see also, id.</i> at G-021 (¶ 0113) (“Preferably, a gas- or water-tight (waterproof or water-resistant) seal is <i>configured to surround the electrical connection at the electrode terminals</i> within the mounting unit (and the respective operable connection with the sensor electronics) from damage due to moisture, humidity, dirt, and other external factors.”).)¹</p>

¹ Emphasis added throughout unless otherwise noted.

Exhibit O

Claim Chart for U.S. Patent No. 10,980,452

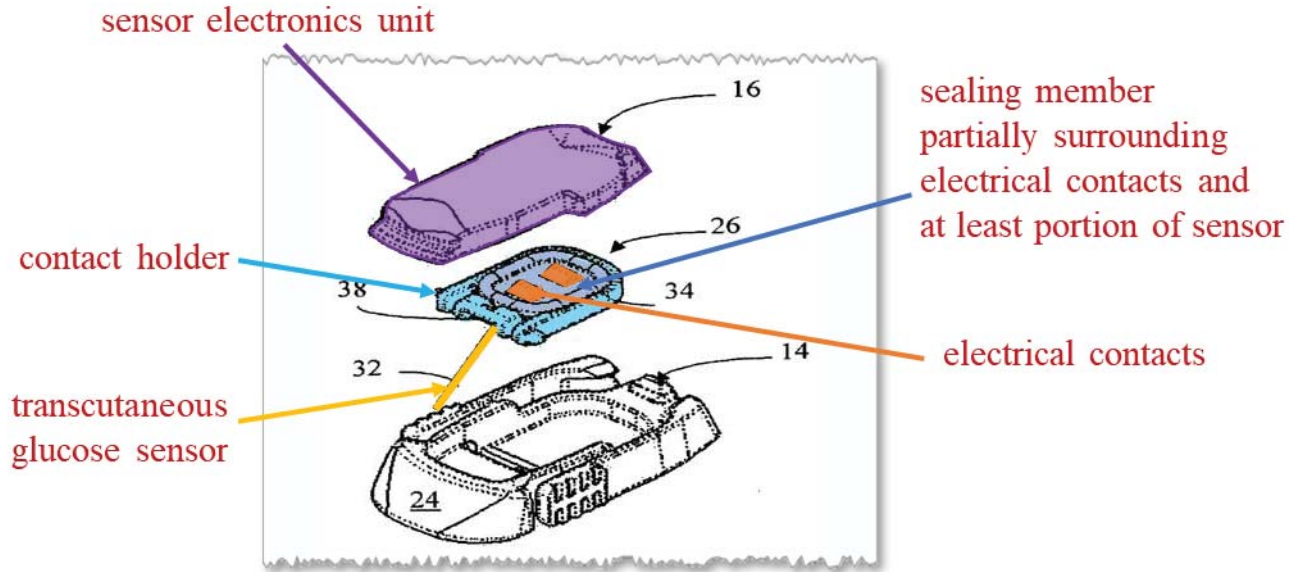
Claim 19	Exemplary Disclosure
<p>portion of the transcutaneous glucose sensor when the transcutaneous glucose sensor is operably connected to the sensor electronics,</p>	<p>Figures 3 and 4 of the 683 Provisional, provided below, illustrate a sealing member (seal 36) configured to at least partially surround an electrical contact (contacts 28) and at least a portion of a transcutaneous glucose sensor (proximal portion 40 of sensor 32) when the transcutaneous glucose sensor is operably connected to the sensor electronics (electronics unit 16).</p>  <p>(683 Provisional at G-052 (Fig. 3) (annotated).)</p>

Exhibit O

Claim Chart for U.S. Patent No. 10,980,452

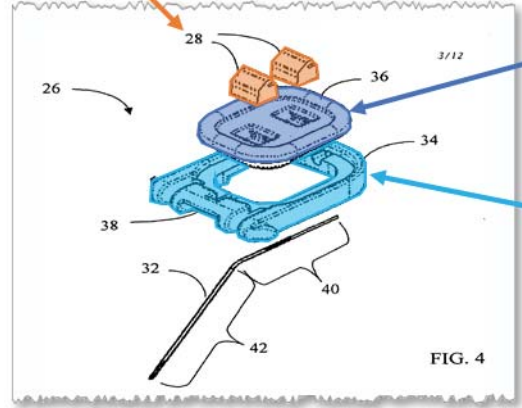
Claim 19	Exemplary Disclosure
	<div data-bbox="569 256 1715 711">  <p>electrical contacts (contacts 28)</p> <p>sealing member configured to at least partially surround the electrical contacts and at least a portion of sensor (seal 36)</p> <p>contact holder</p> <p>FIG. 4</p> </div> <p>(683 Provisional at G-053 (Fig. 4) (annotated).)</p>

Exhibit O

Claim Chart for U.S. Patent No. 10,980,452

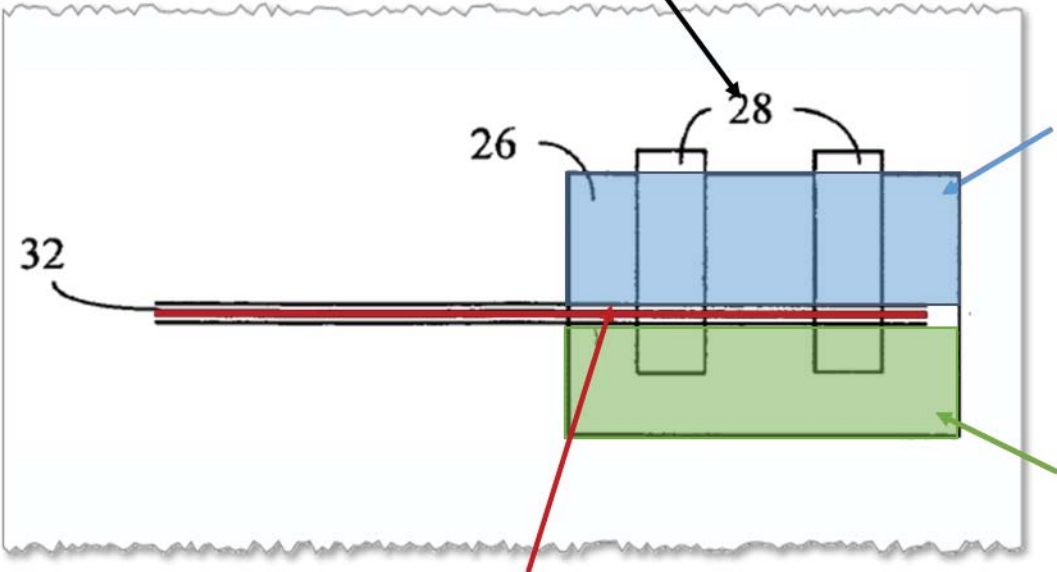
Claim 19	Exemplary Disclosure
	<p data-bbox="772 261 1465 342">electrical contacts at least partially surrounded by sealing member</p>  <p data-bbox="1549 467 1791 589">sealing member upper portion (blue)</p> <p data-bbox="1549 808 1791 930">sealing member lower portion (green)</p> <p data-bbox="615 963 1213 1044">transcutaneous glucose sensor at least partially surrounded by sealing member</p> <p data-bbox="453 1084 1266 1117">(683 Provisional at G-057 (Fig. 7D) (truncated and annotated).)</p>

Exhibit O

Claim Chart for U.S. Patent No. 10,980,452

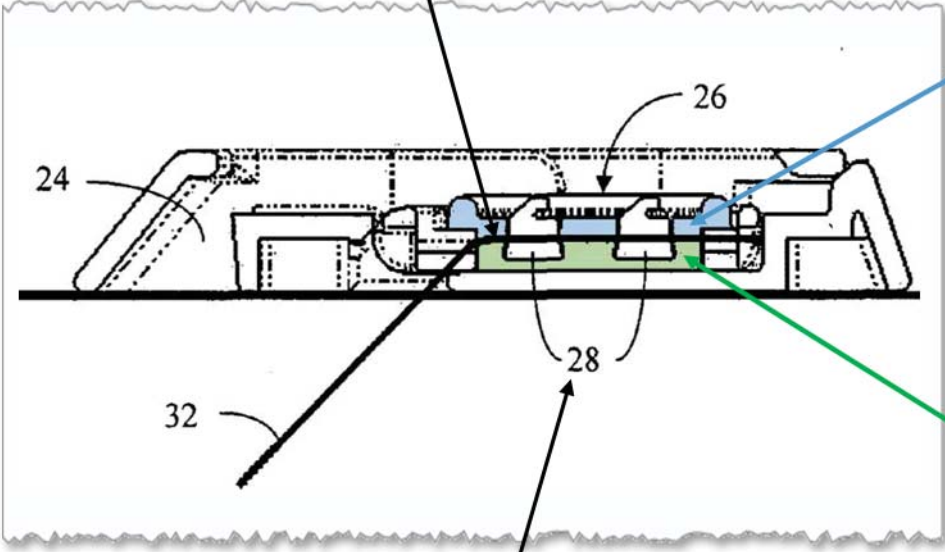
Claim 19	Exemplary Disclosure
	<p>transcutaneous glucose sensor at least partially surrounded by sealing member</p>  <p>sealing member upper portion (blue)</p> <p>sealing member lower portion (green)</p> <p>electrical contacts at least partially surrounded by sealing member</p> <p>(683 Provisional at G-060 (Fig. 10B) (annotated).)</p> <p>Therefore, the 683 Provisional discloses wherein the sealing member at least partially surrounds the electrical contact and at least a portion of the transcutaneous glucose sensor when the transcutaneous glucose sensor is operably connected to the sensor electronics.</p>
[19f] wherein the sealing member	The 683 Provisional discloses this subject matter. The 683 Provisional states “the contact subassembly comprises a seal for protecting the contacts from moisture when the electronics unit is mounted on the mounting

Exhibit O

Claim Chart for U.S. Patent No. 10,980,452

Claim 19	Exemplary Disclosure
substantially seals at least a portion of the electrical contact from moisture, and	<p>unit.” (683 Provisional at G-006 (¶ 0020); <i>see also id.</i> at G-021 (¶ 0113) (“Preferably, a gas- or water-tight (waterproof or water-resistant) seal is configured to surround the electrical connection at the electrode terminals within the mounting unit, such as is described in more detail with reference to Fig. 4, in order to protect the electrodes (and the respective operable connection with the sensor electronics) from damage due to moisture, humidity, dirt, and other external environmental factors.”); <i>id.</i> at G-023 (¶ 0118) (“A seal 36, also referred to as a seal ring, fits within the contact holder 34 and provides a gas-tight seal configured to protect the contacts 28 from outside moisture that can cause corrosion of the contacts and their conductive properties.”).)</p> <p>Therefore, the 683 Provisional discloses wherein the sealing member substantially seals at least a portion of the electrical contact from moisture.</p>
[19g] wherein an ex vivo portion of the transcutaneous glucose sensor is sandwiched between the sealing member upper portion and the sealing member lower portion; and	<p>The 683 Provisional discloses this subject matter. The 683 Provisional states that “a gas- or water-tight (waterproof or water-resistant) seal is configured to surround the electrical connection at the electrode terminals within the mounting unit, such as is described in more detail with reference to Fig. 4”. (683 Provisional at p. G-021 (¶ 0113); <i>see also, id.</i> at G-023 (¶ 0118) (“One of ordinary skill in the art appreciates that a variety of designs can be employed to provide a seal surrounding the electrical contacts . . .”).) A POSITA would have understood that the seal surrounding the electrical contacts also would sandwich an ex vivo portion of the sensor, as shown in Figures 7D and 10B.</p> <p>Figures 7D and 10B of the 683 Provisional, provided below, illustrate an ex vivo portion of a transcutaneous glucose sensor (proximal portion 40 of sensor 32) sandwiched between a sealing member upper portion and a sealing member lower portion.</p>

Exhibit O

Claim Chart for U.S. Patent No. 10,980,452

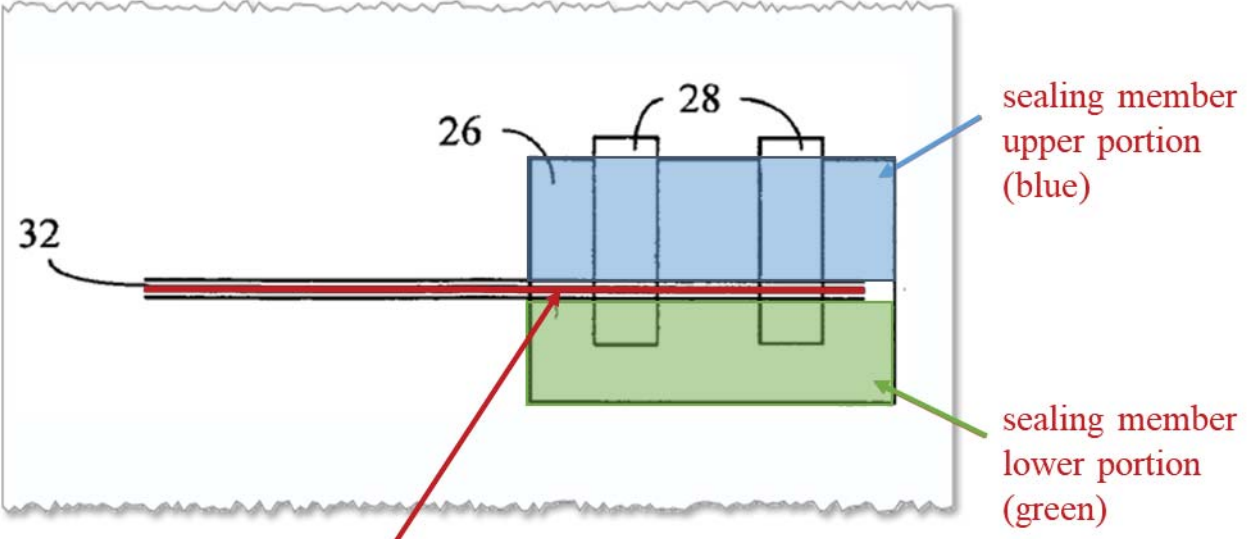
Claim 19	Exemplary Disclosure
	 <p>ex vivo portion of transcutaneous glucose sensor sandwiched between sealing member upper and lower portions</p> <p>(683 Provisional at G-057 (Fig. 7D) (annotated).)</p>

Exhibit O

Claim Chart for U.S. Patent No. 10,980,452

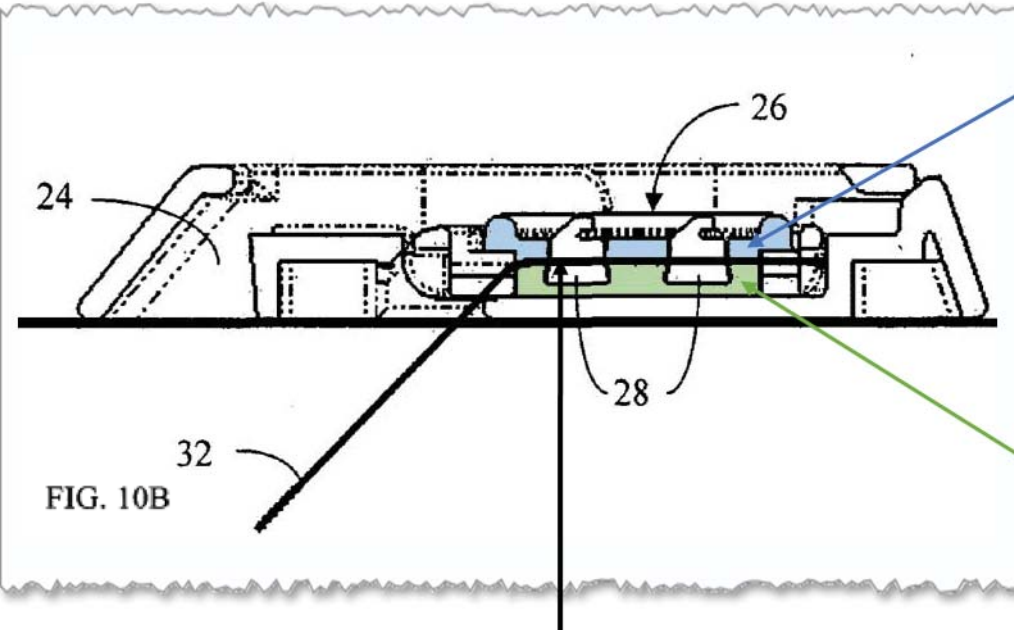
Claim 19	Exemplary Disclosure
	 <p>FIG. 10B</p> <p>sealing member upper portion (blue)</p> <p>sealing member lower portion (green)</p> <p>ex vivo portion of transcutaneous glucose sensor is sandwiched between sealing member upper and lower portions</p> <p>(683 Provisional at G-060 (Fig. 10B) (annotated).)</p> <p>Therefore, the 683 Provisional discloses an ex vivo portion of the transcutaneous glucose sensor sandwiched between the sealing member upper portion and the sealing member lower portion.</p>
<p>[19h] a contact holder over which the sealing member and the</p>	<p>The 683 Provisional discloses this subject matter. The 683 Provisional states that “[t]he contact subassembly 26 includes a contact holder” and that “[a] seal 36, also referred to as a seal ring, fits within the contact holder.” (683 Provisional at G-023 (¶ 0118).) The 683 Provisional further states that “contacts 28 fit within the seal 36 and provide for electrical connection between the sensor 32 and the electronics unit.” (<i>Id.</i> (¶ 0119).) As discussed with respect to claim element 19a, the 683 Provisional discloses a transcutaneous glucose sensor 32.</p>

Exhibit O

Claim Chart for U.S. Patent No. 10,980,452

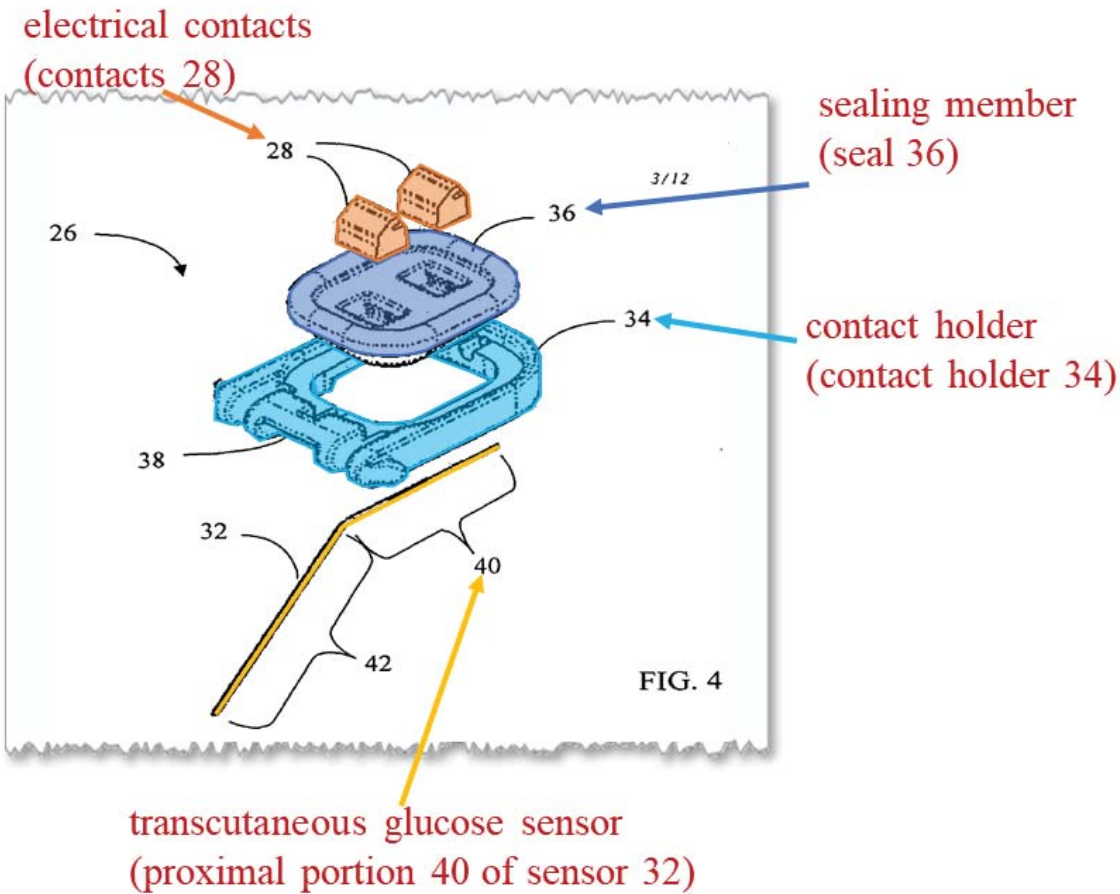
Claim 19	Exemplary Disclosure
transcutaneous glucose sensor are at least partially located.	<p>Figure 4 of the 683 Provisional, provided below, illustrates a contact holder (contact holder 34) over which a sealing member (seal 36) and a transcutaneous glucose sensor (proximal portion 40 of sensor 32) are at least partially located.</p>  <p>FIG. 4</p> <p>(683 Provisional at G-053 (Fig. 4) (annotated).)</p>

Exhibit O

Claim Chart for U.S. Patent No. 10,980,452

Claim 19	Exemplary Disclosure
	Therefore, the 683 Provisional discloses a contact holder over which the sealing member and the transcutaneous glucose sensor are at least partially located.

EXHIBIT 11

Anlage TW V 1
Abbott GmbH / DexCom Inc.
LG Mannheim - 7 O 79/21
Taylor Wessing

DECLARATION OF HON. TIMOTHY K. LEWIS

I. INTRODUCTION

A. The Writer

1. My name is Timothy K. Lewis. I am a former federal judge.
2. I was appointed to serve on the United States District Court for the Western District of Pennsylvania by President George H.W. Bush in 1991. In 1992, President Bush elevated me to serve on the United States Court of Appeals for the Third Circuit, which hears appeals from the district courts in Pennsylvania, New Jersey, Delaware, and the Virgin Islands.
3. Prior to my federal judicial service, I served as a prosecutor in the Office of the United States Attorney for the Western District of Pennsylvania, and as a trial attorney in the Office of the District Attorney for Allegheny County, Pennsylvania.
4. Since I left the bench, I have held the position of Counsel at the Philadelphia-based litigation firm Schnader Harrison Segal & Lewis. At various times I have been resident in its Washington, DC, Pittsburgh, and Philadelphia offices. I have served as the co-chair of the firm's Appellate Practice Group as well as its Alternative Dispute Resolution Practice Group. I provide strategic counseling in various federal and state appellate matters throughout the United States, and I serve as an arbitrator and a mediator in domestic and international complex commercial disputes.
5. I have taught courses on appellate advocacy and adjudication, which included a focus on federal jurisdiction, at the University of Pittsburgh School of Law and as a member of the faculty at Continuing Legal Education programs throughout the

United States. I have also served as an instructor in trial advocacy at the Attorney General's Advocacy Institute at the United States Department of Justice.

6. I have served on the Boards of many organizations dedicated to issues of law and policy in the United States, including the American Constitution Society, the Constitution Project, the Georgetown University Law Center Supreme Court Institute, the Bernard G. Segal Institute for Appellate Advocacy, the Public Interest Law Center of Philadelphia, the International Institute for Conflict Prevention and Resolution, the American Arbitration Association, and others.

7. I have testified before the United States House of Representatives and the United States Senate on numerous occasions about matters affecting the federal judiciary, civil and criminal justice reform, the qualifications of presidential nominees to district and circuit courts and the United States Supreme Court, and most recently about the failure of the Senate Judiciary Committee to accord a Supreme Court nominee the tradition and courtesy of a hearing.

8. I have authored articles, editorials, briefs and book chapters that concerned the function, the independence, and the authority of federal courts and federal judges. I have also previously offered my expert opinion in matters pending before federal courts in the United States and in Europe.

9. I am a member of the American Law Institute, which drafts and publishes, among other things, Restatements of the Law. I am also a member of the American Academy of Appellate Lawyers; the Pennsylvania Interbranch Commission on Gender, Racial and Ethnic Fairness in the Courts; the College of Commercial Arbitrators; as well as other organizations focused on improving our courts and our conflict resolution efforts.

10. I received my undergraduate degree in Political Science from Tufts University in 1976. I received my law degree, with honors, from Duquesne University School of Law in 1980.

11. I have been a member in good standing of the Bar of the Commonwealth of Pennsylvania since 1980.

12. My full *curriculum vitae* is attached hereto as Exhibit A.

B. Conflicts of Interest

13. I have had no prior involvement with the parties or counsel in the present litigation or related cases in U.S. or other courts.

14. I am unaware of any conflict of interest that would prevent me from providing impartial expert opinions in the present litigation.

C. This Report

15. I have been retained as an expert by Abbott Laboratories, and its subsidiaries Abbott Diabetes Care Inc. (“ADC”) and Abbott GmbH (collectively, “Abbott”), to provide my opinions, as a former judge of the United States District Court for the Western District of Pennsylvania and the United States Court of Appeals for the Third Circuit, with respect to certain issues of contract interpretation.

16. Specifically, I have been asked to provide my opinions regarding the interpretation, under Delaware law, of certain provisions in a Settlement and License Agreement entered into by ADC and DexCom, Inc. (“DexCom”) on July 2, 2014 (the “SLA”).

17. The opinions provided here are my own and reflect my independent review of the SLA as well as federal and Delaware caselaw.

18. During my career, I have handled hundreds of matters involving interpretation of contracts, including matters involving questions of Delaware contract law. I have done so as a federal judge, arbitrator, mediator, and as a private practitioner.

II. BACKGROUND

19. I have been asked to assume the following facts as true for the purposes of my analysis:

20. Between 2005 and 2014, ADC and DexCom were involved in a number of patent infringement lawsuits in the United States District Court for the District of Delaware, as well as patent challenges in the U.S. Patent and Trademark Office, regarding patents and technology in the field of continuous glucose monitors (“CGMs”) for treatment of diabetes.

21. On July 2, 2014, to settle all then-pending disputes between them, ADC and DexCom entered into the SLA. The SLA provided a mutual covenant-not-to-sue for patent infringement with respect to certain CGM products until March 31, 2021, as well as licenses to certain defined patents until the earlier of the expiration of those patents, or December 31, 2025.

22. More specifically, Paragraph C.2 of the SLA provides that “[s]ubject to ADC’s material compliance with the terms and conditions of this Agreement, DexCom hereby grants ADC a royalty-free, worldwide, non-exclusive, non-sublicensable license under DexCom Licensed Patents to make, have made, use, offer for sale, sell, distribute, import, and have imported ADC Products.” (SLA, ¶ C.2.)

23. For purposes of this license provision, ADC Products are defined as follows:

“ADC Products” means (a) an electrochemical sensor, made by or for ADC, using an enzymatic reaction and using an osmium mediator to transfer electrons to an electroactive surface for measurement of glucose concentration that is placed in vivo (other than in whole blood) (“ADC In Vivo Sensors”); or (b) if used with ADC In Vivo Sensors, any or all of the following (or any combination of ADC In Vivo Sensors with any or all of the following): (i) a sensor delivery unit, made or customized by or for ADC, for placement of ADC In Vivo Sensors; (ii) a radio frequency communication system, made or customized by or for ADC, that connects to ADC In Vivo Sensors; or (iii) hardware or software, made or customized by or for ADC, for determining, processing, monitoring or displaying glucose values obtained from ADC In Vivo Sensors ((i) - (iii) collectively “ADC Components”); provided, however, that “ADC Products” do not include DexCom In Vivo Sensors. “ADC Products” also do not include Ancillary Products. For the avoidance of doubt, if ADC Products are used in combination with Ancillary Products, then neither such Ancillary Products nor the combination shall be included within the definition of ADC Products, but the ADC Products themselves will continue to be included within the definition of ADC Products.

(SLA, ¶ A.3.)

24. The SLA in turn defines DexCom Licensed Patents as follows:

“DexCom Licensed Patents” means, collectively:

(a) All worldwide patents and patent applications (including any provisional or abandoned patent applications) that DexCom owns or has the right to enforce or direct enforcement of (either solely or jointly with one or more other persons or entities) as of the Effective Date that have an actual filing date before January 1, 2005, excluding those patents and patent applications identified on Exhibit A;

(b) All worldwide patents that DexCom owns or has the right to enforce or direct enforcement of (either solely or jointly with one or more other persons or entities) that (i) have issued as of the Effective Date and that, as of May 15, 2014 claimed, or at any time thereafter claim, priority (in whole or in part) to any of the patents or patent applications captured in subsection (a), or (ii) issue in the future from any patent applications currently pending or subsequently filed (including continuations, continuations-in-part, and divisionals) that, as of May 15, 2014 claimed, or at any time thereafter claim, priority (in whole or in part) to any of the patents or patent applications captured in subsection (a);

(c) A claim in a continuation, continuation-in-part, divisional or any other worldwide patent claiming priority to a patent captured in subsection (b),

but not claiming priority to a patent or application captured in subsection (a), if the following is true: either (i) the claim is fully supported and enabled in the manner required under 35 U.S.C. § 112 (or equivalent standard in jurisdictions outside the United States) by a patent or patent application captured in subsection (a); or (ii) the claim is an obvious variant (or equivalent standard in jurisdictions outside the United States) of the subject matter of a patent or patent application captured in subsection (a); and

(d) All reissues, reexamination certificates, *inter partes* review certificates, results of oppositions, renewals, patent term extensions, patent term adjustments, and corrections of or to the patents and patent applications captured in subsections (a) and (b), and claims satisfying the criteria in either of subsections (c)(i) or (c)(ii) in all reissues, reexamination certificates, *inter partes* review certificates, results of oppositions, renewals, patent term extensions, patent term adjustments, and corrections of or to the patents captured in subsection (c).

Continuations, continuations-in-part, divisionals and other patents claiming priority to the patents captured in subsection (b), but not claiming priority to any of the patents or patent applications captured in subsection (a), are excluded from the definition of DexCom Licensed Patents, except to the extent they have claims that satisfy the requirements of subsection (c).

(SLA, ¶ A.13.)

25. In addition to the license, DexCom provided ADC with a warranty and representation that it had not obtained and would not obtain issuance of patent claims meeting certain defined characteristics but that were excluded from the definition of DexCom Licensed Patents, with the sole remedy for DexCom's breach being that such patent claims would be deemed licensed "on royalty-free, non-exclusive and non-sublicensable basis," consistent with the license provision in ¶ C.2. (SLA, ¶ H.3.) This warranty and representation is stated below:

Dexcom [*sic*] warrants and represents that it has not obtained and shall not obtain the issuance of a patent claim that is both (a) either (i) fully supported and enabled in the manner required under 35 U.S.C. § 112 (or equivalent standard in jurisdictions outside the United States) by a patent or patent application captured in subsection (a) of Paragraph A.13, or (ii) an obvious variant (or equivalent standard in jurisdictions outside the United States) of the subject matter of a patent or patent application captured in subsection

(a) of Paragraph A.13; and (b) excluded from the definition of DexCom Licensed Patents in Paragraph A.13. If DexCom breaches this warranty and representation by obtaining issuance of such a claim, ADC shall as its sole remedy be deemed licensed to such claim on a royalty-free, non-exclusive and non-sublicensable basis (*i.e.*, consistent [*sic*] with Paragraph C.2 of the Agreement).

(SLA, ¶ H.3.) I refer to this warranty and representation throughout this declaration as the “¶ H.3 Warranty.”

26. The SLA provides mechanisms for Dispute Resolution, including requirements for provision of notice and meetings between the parties. (SLA, ¶ J.1.) However, the exercise of some of the remedies—including the license deeming provision in the event of breach of the ¶ H.3 Warranty—is considered “self-executing.” (SLA, ¶ J.2.)

27. With respect to the Governing Law under which the Agreement is to be “construed, governed and interpreted,” the SLA states:

This Agreement or the performance, enforcement, breach, or termination hereof shall be construed, governed, and interpreted in accordance with the laws of the State of Delaware and the United States of America without regard to their conflict of laws principles, except that questions affecting the construction and effect of any patent shall be determined by the law of the country in which the patent shall have been granted.

(SLA, ¶ K.7.)

28. Importantly, with respect to the Choice of Forum for “any dispute arising from or under or relating to” the Agreement, the SLA provides:

The United States Federal District Court for the District of Delaware shall have exclusive jurisdiction over any dispute arising from or under or relating to this Agreement, to the extent permitted by law. The state courts of Delaware shall have exclusive jurisdiction over any dispute arising from or under or relating to this Agreement, to the extent subject matter jurisdiction is lacking in federal courts. For any dispute arising from or under or relating to this Agreement, each Party stipulates to personal jurisdiction and venue in the state of Delaware. For any dispute brought in Delaware that arises from or under or relates to this Agreement, each Party waives any defenses based

upon lack of personal jurisdiction, lack of venue, or forum non conveniens, and waives the right to seek transfer out of Delaware.

(SLA, ¶ J.4.) This type of clause is also known as a “forum selection clause” under U.S. law.

29. The mutual covenant-not-to-sue under the SLA expired on March 31, 2021. Subsequently, on July 5, 2021, DexCom commenced suit *not* in a Delaware state or federal court but in the Mannheim Regional Court in Mannheim, Germany, accusing Abbott Laboratories, ADC and Abbott GmbH of infringing the following European patents by their activities with respect to sale of Abbott’s Freestyle Libre (“FSL”) range of CGM products in Germany: EP 3 435 866 B1 (“EP866”), EP 2 829 244 B1 (“EP244”), EP 2 914 159 B1 (“EP159”) and EP 3 782 539 B1 (“EP539”) (collectively, “Asserted DexCom EPs”), each of which on its face identifies its “Proprietor” as “Dexcom, Inc.”¹

30. Each of ADC, Abbott Laboratories and Abbott GmbH are accused in the Mannheim action of infringing the Asserted DexCom EPs through the same sales of FSL products in Germany.

31. I understand that Abbott contends that the claims of the patents asserted in the Mannheim action were obtained in breach of DexCom’s warranty, and therefore should be deemed licensed, under the ¶ H.3 Warranty.

¹ DexCom also commenced suit in the United States District Court for the Western District of Texas accusing ADC itself, as well as another affiliate, Abbott Diabetes Care Sales Corp., of infringing certain DexCom U.S. patents by their activities in the U.S. with respect to Abbott’s FSL range of CGM products. Shortly thereafter, ADC and certain of its affiliates brought suit against DexCom and certain of its affiliates in the United States (Delaware), Germany and the U.K. for patent infringement with respect to DexCom’s own CGM products. DexCom has since counterclaimed for infringement of its own patents in the U.K. action.

III. QUESTIONS PRESENTED, MATERIALS CONSIDERED, AND SUMMARY OF OPINIONS

32. I have been asked to provide my opinions with respect to the following three categories regarding the SLA and the Asserted DexCom EPs:

1. Choice of Forum

(a) What court should resolve disputes over whether the Asserted DexCom EPs were obtained in breach of DexCom's warranty and, therefore, are deemed licensed under the ¶ H.3 Warranty? (b) Does DexCom's infringement action against Abbott in Mannheim raise such a dispute?

2. What Law Applies

(a) Which jurisdiction's law applies when deciding whether the asserted claims of the Asserted DexCom EPs are each "an *obvious variant* ... of the subject matter of a patent or patent application captured in subsection (a) of Paragraph A. 13" of the SLA so as to breach the ¶ H.3 Warranty? (b) What standard should apply to the question? (c) What time period should apply?

3. "Have Made" and "Have Imported" Rights

(a) What are ADC's "have made" and "have imported" license rights under ¶ C.2 of the SLA? (b) Are the entities manufacturing, importing and first selling in the European Union the FSL products to be sold in Germany operating within the scope of those rights?

33. In providing my opinions with respect to these areas, I have considered the terms of the SLA; caselaw precedent regarding interpretation of patent licenses under Delaware and U.S. law; and my own experience and expertise. I have also been provided

with information regarding the product flow for FSL products from manufacture to sale in Germany, which I have included in this Report.

34. My conclusions with respect to these questions, as explained further below, are briefly summarized as follows:

- (1) According to the Choice of Forum clause in ¶ J.4 of the SLA, disputes over whether the Asserted DexCom EPs were obtained in breach of DexCom's warranty should be resolved in the United States District Court for the District of Delaware or, to the extent subject matter jurisdiction is lacking in that federal court, in the state courts of Delaware. DexCom's infringement action against Abbott in Mannheim raises such a dispute. This applies to the entirety of the infringement action (including, without limitation, the license defense), and against each Abbott entity (ADC, Abbott Laboratories and Abbott GmbH).
- (2) A court should apply the European law equivalent of the U.S. law determination of patent obviousness under 35 U.S.C. § 103 in the U.S. (*i.e.*, the court should apply European law regarding inventive step) when deciding whether the asserted claims are each "an *obvious variant*." The relevant time period for the determination is as of the SLA's Effective Date (July 2, 2014), or such later date as the claim was or is issued to DexCom.
- (3) Generally speaking, ADC Inc.'s "have made" and "have imported" license rights under ¶ C.2 of the SLA permit it to engage third parties, whether affiliates or independent entities, to make and import the ADC Products for it. Based on the information I have reviewed regarding the flow of FSL

products from manufacture to first sale in the EU, in my opinion, the entities undertaking the manufacture, import, and first sale into the EU of the FSL products to be sold in Germany are doing so within the scope of ADC's "have made" and "have imported" rights.

IV. CONTRACT INTERPRETATION STANDARDS UNDER DELAWARE LAW

35. A court determining the scope of a contractual obligation under Delaware law must "give priority to the parties' intentions as reflected in the four corners of the agreement." *U.S. Gypsum Co. v. Quigley Co. (In re G-I Holdings, Inc.)*, 755 F.3d 195, 202 (3d Cir. 2014) (quoting *GMG Capital Invs., LLC v. Athenian Venture Partners I, L.P.*, 36 A.3d 776, 779 (Del. 2012)). "In upholding the intentions of the parties, a court must construe the agreement as a whole, giving effect to all provisions therein." *Id.* (citing *E.I. du Pont de Nemours & Co., Inc. v. Shell Oil Co.*, 498 A.2d 1108, 1113 (Del. 1985)); *see also Lorillard Tobacco Co. v. Am. Legacy Found.*, 903 A.2d 728, 739 (Del. 2006)-(observing that "the role of a court is to effectuate the parties' intent"); *In re Viking Pump, Inc.*, 148 A.3d 633, 648 (Del. 2016) (noting that, absent ambiguity, the court applying Delaware contract law "will give priority to the parties' intentions as reflected in the four corners of the agreement, construing the agreement as a whole and giving effect to all its provisions").

36. "[A] contract is ambiguous only when the provisions in controversy are reasonably or fairly susceptible of different interpretations or may have two or more different meanings." *Rhone-Poulenc Basic Chems. Co. v. Am. Motorist Ins. Co.*, 616 A.2d 1192, 1196 (Del. 1992); *see also MBIA Ins. Corp. v. Royal Indem. Co.*, 426 F.3d 204, 210 (3d Cir. 2005). By contrast, a contract is unambiguous when "the plain, common, and ordinary meaning of the words lends itself to only one reasonable interpretation." *Sassano v. CIBC*

World Mkts. Corp., 948 A.2d 453, 462 (Del. Ch. 2008). “A contract is not rendered ambiguous simply because the parties do not agree upon its proper construction.” *Rhone-Poulenc*, 616 A.2d at 1196; *see also MBIA Ins. Corp.*, 426 F.3d at 210 (noting that Delaware contract law requires that “[w]ords are to be given their ordinary meaning and should not be ‘tortured’ to impart ambiguity where none exists”).

V. DISCUSSION

A. Choice of Forum

37. To the extent DexCom disputes that it has breached the ¶ H.3 Warranty by obtaining the Asserted DexCom EPs, the SLA requires that such dispute be resolved in the Delaware federal or state courts.

38. As discussed above, the SLA’s Choice of Forum provision provides as follows:

The United States Federal District Court for the District of Delaware shall have exclusive jurisdiction over *any dispute arising from or under or relating to this Agreement*, to the extent permitted by law. The state courts of Delaware shall have exclusive jurisdiction over *any dispute arising from or under or relating to this Agreement*, to the extent subject matter jurisdiction is lacking in federal courts. For any dispute arising from or under or relating to this Agreement, each Party stipulates to personal jurisdiction and venue in the state of Delaware. For any dispute brought in Delaware that arises from or under or relates to this Agreement, each Party waives any defenses based upon lack of personal jurisdiction, lack of venue, or forum non conveniens, and waives the right to seek transfer out of Delaware.

(SLA, ¶ J.4 (emphasis added).)

39. This clause is unambiguous. “[A]ny dispute arising from or under or relating to” the SLA is to be resolved by either the federal or state courts of Delaware.² Under Delaware contracts law, a court should effectuate the parties’ clear intent as reflected in this clause. *See Lorillard*, 903 A.2d at 739.

² I offer no opinion which court—state or federal—should resolve the dispute.

40. DexCom's infringement action against ADC in Mannheim is a dispute that "aris[es] from or under or relating to" the SLA and, as such, should be resolved by a Delaware court pursuant to the Choice of Forum clause. That is because, under U.S. law applicable in Delaware, patent infringement disputes, such as whether goods are covered by the licensed patents and patent validity issues, are considered to "arise from" license agreements. *See, e.g., Texas Instruments Inc. v. Tessera, Inc.*, 231 F.3d 1325, 1331 (Fed. Cir. 2000). Once a party to a patent license agreement (here ADC) raises a non-frivolous defense that allegedly infringing activities are licensed, the Choice of Forum clause applies. *See Atlantic Marine Const. Co. v. U.S. Dist. Court for Western Dist. of Texas*, 571 U.S. 49, 63 (2013) (U.S. Supreme Court) ("The 'enforcement of valid forum-selection clauses, bargained for by the parties, protects their legitimate expectations and furthers vital interest of the justice system.'" (citation omitted); *General Protecht Group v. Leviton Mfg. Co.*, 651 F.3d 1355, 1359 (Fed. Cir. 2011) (holding that, when the "case presents a non-frivolous dispute regarding the scope of a patent license" that "will determine whether the patentee can sustain its suit for infringement," "there is no question" that the dispute "relates to or arises out of" the agreement, and "[t]he forum selection clause therefore applies.").³ Put simply, an act cannot be infringing if it is licensed, so DexCom's infringement action relates to and arises from the license where, as here, ADC has raised a license defense.

41. Furthermore, DexCom, a signatory to an agreement, does not avoid its agreed-upon forum selection clause merely by making allegations against non-signatories

³ The United States Court of Appeals for the Federal Circuit has exclusive jurisdiction to consider appeals from cases arising under U.S. patent laws.

that are “affiliates of” or otherwise have an “intertwined” relationship with a signatory. Accordingly, DexCom’s accusations against non-signatories Abbott Laboratories and Abbott GmbH do not mean that the Choice of Forum clause should not apply to its infringement action. As I have been informed, Abbott Laboratories and Abbott GmbH are each affiliates of the signatory ADC. Abbott Laboratories, Abbott GmbH, and ADC are also all accused by DexCom in the Mannheim action of infringing the Asserted DexCom EPs through the exact same sales of FSL products in Germany. It would appear, therefore, that DexCom’s own allegations indicate that these entities are “intertwined.” As such, it is my opinion that the Choice of Forum clause in the SLA, to which DexCom agreed, applies to DexCom’s infringement assertions against all of ADC, Abbott Laboratories, and Abbott GmbH. In analogous circumstances, at least one U.S. court has held that a licensee’s customer could enforce a forum selection clause in a suit brought by the licensor. *See Uniloc USA, Inc. v. Cisco Sys., Inc.*, No. 6:15-cv-1175-JRG, 2017 WL 959856, *4 (E.D. Tex. Mar. 13, 2017); *see also Brady v. RSM McGladrey, Inc.*, C.A. No. M10-108, 2011 WL 13250551, *2 (S.D. Tex. Mar. 8, 2011) (“[A] plaintiff signatory to an agreement who asserts claims against a defendant signatory, which claims are covered by the agreement and the forum selection clause therein, cannot avoid application of the clause by making some allegations of conduct by a non-signatory, non-defendant who has an ‘intertwined’ relationship with the parties.”).

42. For all these reasons, it is my opinion that DexCom’s case in the Mannheim action against ADC, Abbott Laboratories and Abbott GmbH is subject to the Choice of Forum selection clause in ¶ J.4 of the SLA. It is also my view that any disputes over whether DexCom breached its warranty by obtaining the Asserted DexCom EPs, and whether those

patents should be deemed licensed—as well as any related patent issues (such as whether the Asserted DexCom EPs constitute “obvious variants” of the subject matter of DexCom’s § A.13(a) patents, *see* Section B, below)—should be decided by the Delaware federal or state courts.

B. The question whether the Asserted DexCom EPs’ claims satisfy the “obvious variant” provision of the ¶ H.3 Warranty should be determined under the European law equivalent to the U.S. law of obviousness under 35 U.S.C. § 103 (*i.e.*, inventive step), applied as of the Effective Date of the SLA or such later date as each claim at issue was obtained

43. For the reasons discussed in further detail below, it is my opinion that a Delaware federal or state court should apply the European law applicable to European patents (which I understand to be defined by the European Patent Convention). More specifically, the question whether the asserted DexCom European patent claims in the Mannheim action satisfy the “obvious variant” provision in the ¶ H.3 Warranty should be determined by a Delaware federal or state court under the laws applicable to European patents. In doing so, the court should apply the equivalent under European law to the U.S. law of obviousness under 35 U.S.C. § 103. The relevant date for considering whether a claim is an “obvious variant” of the subject matter in a ¶ A.13(a) patent for purposes of the ¶ H.3 Warranty is the Effective Date of the SLA (July 2, 2014), or such later date as the claim under consideration was or is obtained.

44. In light of the allegations of the Mannheim action and “the plain, common, and ordinary meaning of the words” of the ¶ H.3 Warranty, *see Sassano*, 948 A.2d at 462, I understand the relevant question to be whether each asserted claim of the Asserted DexCom EPs is “an obvious variant (*or equivalent standard in jurisdictions outside the United States*) of the subject matter of a patent or patent application captured in subsection (a) of

Paragraph A.13.” (SLA, ¶ H.3 (emphasis added).) Because the Asserted DexCom EPs are European patents asserted in Germany, a “jurisdiction[] outside the United States,” the “equivalent standard” clause is invoked. The proper standard will therefore be that of European patent law applicable in Germany. As discussed below, I understand the applicable equivalent standard will be that of “inventive step” under European law.

45. Determining whether a patent law claim involves an inventive step under European patent law requires consideration of the “the plain, common, and ordinary meaning of the words” of the Governing Law provision, *see Sassano*, 948 A.2d at 462, and “the law of the country in which the patent shall have been granted,” *i.e.*, the patent laws of Europe as applicable in Germany.

46. In addressing this question, I first consider the context in which the term “obvious variant” is used in the SLA “as a whole and giving effect to all its provisions.” *In re Viking Pump*, 148 A.3d at 648. In that regard, I note that the phrase “obvious variant” appears only twice in the SLA—each time to expand the scope of DexCom patents that are subject to the ¶ C.2 license grant from DexCom to ADC. That the parties included this “obvious variant” concept in the SLA twice (first, in the definition of DexCom Licensed Patents, and second, in the separate ¶ H.3 Warranty), and also included both a representative (as to past and present) and a promissory (future) warranty, indicates that “obvious variant” is a material term relating to the intended scope of the DexCom Licensed Patents and the scope of ADC’s license rights. Furthermore, each use adds to the scope of patents licensed to ADC under the definition of DexCom Licensed Patents and the ¶ C.2 license grant in a distinct way, and there is no overlap between the two uses.

47. In the definition of DexCom Licensed Patents, the first use of the “obvious variant” concept covers claims in patents claiming priority to “subsection (b) patents.” Subsection (b) patents are patents controlled by DexCom as of the Effective Date of the SLA that had an actual filing date after January 1, 2005, but themselves claim priority to “subsection (a) patents.” Subsection (c) of the definition of DexCom Licensed Patents includes such claims if “the claim is an obvious variant (or equivalent standard in jurisdictions outside the United States) of the subject matter of a patent or patent application captured in subsection (a).” (SLA ¶ A.13(c)). This use of the “obvious variant” test is the more limited use, as it remains tied to a claim of priority to other DexCom Licensed Patents.

48. The second use appears in the ¶ H.3 Warranty, which applies the same test in a broader context. Specifically, it applies to any patent claims obtained by DexCom, without limitation (including whether or not claiming priority to already licensed patents), that meet any of the relevant tests and are excluded from the definition of DexCom Licensed Patents. The ¶ H.3 Warranty is both an affirmative warranty (guaranteeing the truth of a past or present fact—here, that DexCom “*has not*” obtained the issuance of a precluded patent claim), and a promissory warranty (relating to a future undertaking that the party warrants will be carried out—here, that DexCom “*shall not*” obtain the issuance of a precluded patent claim). The importance of the ¶ H.3 Warranty is underscored by the self-executing remedy provided for its breach, providing ADC with a license consistent with the ¶ C.2 license to any patent claims obtained in breach of the ¶ H.3 Warranty.

49. Having highlighted the importance of the ¶ H.3 Warranty (and thus the “obvious variant” test therein), it is important to understand the meaning of the “obvious

variant” test and how it is meant to be applied. I again note that the contract language refers to “an obvious variant (*or equivalent standard in jurisdictions outside the United States ...*).” This shows that “obvious variant” is intended to refer to an established legal standard, rather than just the ordinary meaning of obviousness in the English language.

50. The relevant date for consideration of whether a particular patent claim is an “obvious variant” of the subject matter of a ¶ A.13(a) patent or patent application for purposes of the ¶ H.3 Warranty is the Effective Date of the SLA (July 2, 2014), or such later date as the claim at issue is acquired by DexCom. Paragraph H.3 states that “Dexcom [*sic*] warrants and represents that it *has not* obtained ... the issuance of a patent claim *that is* ... an obvious variant (or equivalent standard in jurisdictions outside the United States) of the subject matter of a patent or patent application captured in subsection (a) of Paragraph A.13” (emphasis added). In other words, the question for these patents is whether the claim covers subject matter that is an “obvious variant” of ¶ A.13(a) patent or patent application in view of what was known by those skilled in the art at the Effective Date of the agreement on July 2, 2014.

51. Furthermore, as discussed above, the ¶ H.3 Warranty includes a promissory warranty relating to a *future undertaking*—that DexCom “shall not” obtain the issuance of a patent claim that *is* an “obvious variant.” This is intended to prevent DexCom from obtaining later patent claims (after the Effective Date) that are “obvious variants” of ¶ A.13(a) patent or patent application.

52. Accordingly, and to reiterate what I stated above, it is my opinion that in determining whether the Asserted DexCom EPs were obtained by DexCom in breach of the ¶ H.3 Warranty, and therefore should be deemed licensed, the Delaware federal or

state court should consider whether the claims of those patents describe “obvious variants” of the subject matter of any DexCom ¶ A.13(a) patents or patent applications. In doing so, the court should apply the European law equivalent of the U.S. law of obviousness under 35 U.S.C. § 103. I understand the European law equivalent is the legal standard for determining whether a claim involves an “inventive step.” The relevant date for consideration of whether there is an inventive step is the Effective Date of the SLA or the date the patent claim issues, whichever is later.

C. The entities manufacturing, importing (where applicable) and first selling in the EU the FSL products to be sold in Germany are doing so within the scope of ADC’s “have made” and “have imported” rights under the SLA

1. Background

53. I understand that a European patent law expert will separately address the question of whether the Asserted DexCom EPs’ claims were obtained in breach of the ¶ H.3 Warranty because they were “obvious variants” (or the equivalent under European patent law) of DexCom ¶ A.13(a) patents or patent applications. If the Delaware federal or state court deems that they were obtained in breach of the ¶ H.3 Warranty, ADC would “as its sole remedy be deemed licensed to such claim on a royalty-free, non-exclusive and non-sublicensable basis (*i.e.*, consistant [*sic*] with Paragraph C.2 of the Agreement).” (SLA, ¶ H.3.) This remedy is “self-executing.” (SLA, ¶ J.2.) Therefore, assuming a breach of the ¶ H.3 Warranty, ADC should be deemed licensed to the claims of the Asserted DexCom EPs.

54. I am informed that, under the applicable European law, the question whether the activities alleged to be infringing in the Mannheim action infringe the Asserted DexCom EPs depends on whether the first sale of the accused FSL products in

the EU is licensed under the SLA. That, in turn, depends on whether the manufacture or import of the FSL products in the EU, before the first EU sale, is in accordance with the rights granted to ADC in ¶ C.2 of the SLA. According to that provision, ADC's deemed license under the ¶ H.3 Warranty would be "a royalty-free, worldwide, non-exclusive, non-sublicensable license under [the Asserted DexCom EPs] to make, *have made*, use, offer for sale, sell, distribute, import, and *have imported* ADC Products." (SLA, ¶ C.2 (emphasis added).)

55. Because the question whether the manufacture and import into the EU market of Abbott's FSL products is one of construction and interpretation of the license provision in ¶ C.2 and does *not* involve "questions affecting the construction and effect of any patent," according to the "Governing Law" provision of the SLA, that question should be determined "in accordance with the laws of the State of Delaware and the United States of America without regard to their conflict of laws principles." (SLA, ¶ K.7.) Further, as with the question of whether the Asserted DexCom EPs' claims were obtained in breach of the warranty, these questions as to the scope and interpretation of the license provision in ¶ C.2 should be resolved by the same court. (SLA, ¶ J.4.)

56. I have been asked to explain the scope of "have made" and "have imported" rights under ¶ C.2 of the SLA, and provide my opinion as to whether the applicable activities in the flow of the FSL products to be sold in Germany fall within those rights. For the reasons discussed below, it is my opinion that, according to contract laws applicable in Delaware and across the United States, the manufacture and import into the EU market of Abbott's FSL products to be sold in Germany are a valid exercise of ADC's "have made"

and “have imported” rights under ¶ C.2 of the SLA, as applied to the Asserted DexCom EPs by the deemed licensing provision in ¶ H.3 of that Agreement.

2. Applicable law

57. Courts in Delaware and across the U.S. States have considered the scope of “have made” rights under patent license agreements. Although I am not aware that the scope of “have imported” rights has been specifically addressed by U.S. courts, it is my opinion that the same principles that apply to “have made” rights, as outlined below, would also apply to “have imported” rights.

58. One of the most oft-cited cases relating to the scope of “have made” rights is *Cyrix Corp. v. Intel Corp.*, 77 F.3d 1381 (Fed. Cir. 1996), in which the United States Court of Appeals for the Federal Circuit was called upon to consider whether a licensee’s delegation of the manufacture of licensed products to a foreign affiliate was a valid exercise of its “have made” rights under a license. The Federal Circuit held that it was.

59. The facts of *Cyrix* are instructive. In that case, the plaintiff Cyrix Corp. used a company called SGS-Thomson Microelectronics, Inc. (“ST”) as a foundry to manufacture integrated circuit chips containing microprocessors designed by Cyrix. 77 F.3d at 1383. ST was operating under a non-sublicensable license with Intel Corp. under Intel’s patents and patent applications, which permitted ST “to make, *to have made*, to use, to sell (either directly or indirectly), to lease, and to otherwise dispose of” certain licensed products. *Id.* ST initially manufactured the chips itself but, when it was unable to meet Cyrix’s demand, it requested its Italian affiliate, ST-Italy, to manufacture the needed chips, which ST sold to Cyrix. *Id.*

60. Under apprehension of suit from Intel, Cyrix filed a declaratory action, claiming in part that the chips it received from ST were licensed. *Id.* at 1383–84. The district court agreed with ST, holding that the chips manufactured by ST-Italy were made according to ST’s “have made” rights under its agreement with Intel, and that the supply agreement between ST and ST-Italy was not an impermissible sublicense. *Id.* at 1384. Intel appealed, and the Federal Circuit affirmed.

61. Intel argued on appeal that the arrangement between ST and ST-Italy was in effect a sublicense, which was prohibited by the license. *Id.* at 1387. Intel also argued that, under the license’s “have made” rights, ST was permitted only to have product made for itself, not for its customer Cyrix. *Id.* But the Federal Circuit rejected these arguments, holding that it was a valid exercise of ST’s “have made” right under the Intel license to have ST-Italy manufacture product to satisfy ST’s obligations to Cyrix. *Id.* at 1388.

62. These same principles have been discussed with approval and applied in later cases, including in Delaware. For example, in *Intel Corp. v. Broadcom Corp.*, 173 F. Supp. 2d 201 (D. Del. 2001), the United States District Court for the District of Delaware was called upon to resolve the parties’ dispute as to whether defendant Broadcom’s manufacture of products for third-party licensees of Intel was licensed under the “have made” rights granted by Intel to those licensees. Both parties moved for summary judgment (asking the court to rule in their favor without a trial). Broadcom argued that its allegedly infringing manufacture activities were protected from infringement liability as they were a valid exercise of its customers’ “have made” rights. Intel argued that Broadcom was not validly operating under the licensees’ “have made” rights, because it was making off-the-shelf

products that just happened to be purchased by Intel's licensees, rather than actually making products for the licensees.

63. The court first cited *Cyrrix* with approval as defining "have made" rights as follows: "A 'have made' right, which is a right carved from the term 'to make' in 35 U.S.C. § 271(a), provides a licensee with the right to request an unlicensed third-party to manufacture a licensed good for the licensee." 173 F. Supp. 2d at 228 (emphasis added) (citing *Cyrrix*, 77 F.3d at 1386). The court then reviewed the applicable caselaw and circumstances where "have made" rights may apply.

64. The court noted that "[w]hile none of the licenses at issue granted to the licensee the right to sublicense its rights to a third party and in fact are restricted in that regard, it is well settled that rights to a third party can nonetheless be conferred through the valid exercise of a licensee's 'have made' rights." *Id.* at 231 (citation omitted). According to the court, "[h]ave made' rights stem from the basic rights to make, use, and sell that are typically granted in a patent license." *Id.* After reviewing the *Cyrrix* decision, the court summed up that "[t]he 'have made' cases stand for the ... proposition that by exercising their rights to 'have [licensed products] made,' licensees can shield the unlicensed manufacturer who makes the products for them and subsequently sells the products to ... them from infringement liability by impliedly licensing the otherwise infringing actions." *Id.* at 232.

65. Other courts, including those in Delaware, have recognized the same distinction between the valid exercise of "have made" rights (protected), and the incidental sales of products to licensees (not protected). For example, in *Thorn EMI North America, Inc. v. Hyundai Electronics Industries Co.*, No. CIV. A. 94-332-RRM, 1996 WL 33415780 (D.

Del. July 12, 1996), the federal district court in Delaware held that “a foundry commissioned by [the licensee] IBM to manufacture [licensed] products would have the protection of the license agreement,” while “[a] manufacturer of ‘off the shelf’ products is not a foundry” and “[s]uch a manufacturer, therefore, whether or not it sold the products to [licensee] IBM, would not be protected by the agreement.” *Id.* at *6.

66. In summary, these cases stand for the proposition that, where a manufacturer is making a product based on a request from a licensee, that manufacturer is generally immune from patent infringement under the licensee’s express or implied “have made” rights, absent an intention to the contrary.

67. As in *Intel v. Broadcom*, 173 F. Supp. 2d 201 (D. Del. 2001), whether a particular manufacturing arrangement would be covered by the licensee’s “have made” rights is a question of fact for the fact-finder to decide. In considering that question, courts have not imposed any formal requirements on licensees in the exercise of their “have made” rights. On the contrary, in surveying the relevant caselaw, one federal district court recently held that there are no “special requirements on licensees to exercise their have made rights,” and that “[t]his makes sense because the rights are inherent unless plainly disclaimed by the parties, and outsourcing the manufacture of licensed products is a ‘modern industrial reality.’” *Carnegie Mellon Univ. v. LSI Corp.*, C.A. No. 18-cv-04571-JD, 2020 WL 5592990, at *4 (N.D. Cal. Sept. 18, 2020) (quoting *LaserDynamics, Inc. v. Quanta Comput., Inc.*, 694 F.3d 51, 72 (Fed. Cir. 2012)).

68. Thus, this relevant caselaw establishes that the U.S. courts apply a broad and flexible interpretation as to what constitutes exercise of a licensee’s “have made” rights, with a few limited exceptions.


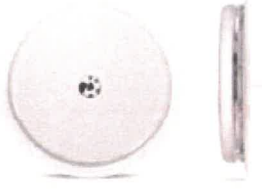

69. As discussed, these cases address the scope of “have made” rights under a patent license. Although I am unaware that the U.S. courts have explicitly considered “have imported” rights, it is my opinion that the same principles discussed above with respect to “have made” rights would apply equally to “have imported” rights.

70. For example, a licensee would validly exercise its “have imported” rights when it has a third party, including an affiliate, import the licensed product for it. *See Cyrix*, 77 F.3d at 1387–88. And as with “have made” rights, there would be no “special requirements on licensees to exercise their have [imported] rights,” in circumstances where outsourcing such import is a “modern industrial reality,” so long as the importer is acting on a “bona fide request” from the licensee, and none of the established exceptions applies. *Carnegie Mellon*, 2020 WL 5592990, at *4.

3. Manufacture and import of Abbott’s FSL products for sale in Germany

71. I have been asked to assume the following facts to be true for the purposes of my analysis:

72. Abbott’s FSL products each include an applicator, an integrated on-body unit that includes a glucose sensor and a transmitter, and a display device (such as a reader or smart device) with proprietary software:

		
Applicator	On-body unit (front and side view) including sensor and transmitter	Display device (reader or smart device) with proprietary software

a. Product flow (on-body units)

73. The manufacture and (where applicable) import of the on-body units for Abbott's FSL products for sale in Germany is conducted according to three separate product flows, depending on which third-party manufacturer ("TPM") is engaged to assemble the final on-body unit, [REDACTED] or [REDACTED], using sensors manufactured by [REDACTED]

74. For on-body units assembled by [REDACTED], an ADC affiliate, [REDACTED], issues purchase orders to [REDACTED], which supplies it with assembled on-body units. For on-body units assembled by [REDACTED] before July 20, 2021, ADC itself issued purchase orders to [REDACTED], which supplied it with assembled on-body units. Since July 20, 2021, [REDACTED] has issued purchase orders to [REDACTED], and is supplied with the assembled on-body units. Each TPM's manufacture is conducted under a supply agreement with Abbott, with [REDACTED] being the Abbott signatory to the agreement with [REDACTED], and ADC being the Abbott signatory to the agreement with [REDACTED].

75. After the TPMs assemble the on-body units, they ship them using third-party shipping companies to another ADC affiliate, [REDACTED], in Germany. In parallel to this physical transfer, the products undergo a series of inter-affiliate sales, first to Abbott Laboratories Vascular Enterprises Limited Partnership (ALVE), [REDACTED] and then on to [REDACTED]. Finally, before the products are sold to customers in Germany, [REDACTED] transfers both the physical product and title to a separate German entity, Abbott GmbH, which operates as the German distributor of the products. Abbott GmbH is identified as the “importer” of the FSL products.



76. I am informed that the above activities of the TPMs and ADC affiliates are performed in accordance with instructions from ADC employees.

77. I am advised that ADC owns all of the intellectual property, including patents, trademarks and trade secrets, associated with the FSL range of products in Europe. I am further advised that ADC also owns the product-related know-how, including design documents, product specifications and manufacturing documents. As such, in connection

with these product flows, according to a license agreement with ALVE, ADC receives a percentage of the net sales of FSL products.

b. Product flow (readers)

78. Although, as with the on-body units, the FSL readers are also sold by [REDACTED] to Abbott GmbH for distribution to customers in Germany with the on-body units, the flow of the readers from manufacture to [REDACTED] is different.

79. In this flow, the raw meters are manufactured by [REDACTED]. The raw meters are then transferred to another TPM [REDACTED], which assembles the raw meters into final reader kits. For the German market, [REDACTED] delivers the raw meters to [REDACTED] in Poland, and the final reader kits are assembled [REDACTED] there. I understand that ADC is the signatory to the supply agreement with [REDACTED], and takes title to, and possession of, the final reader kits from [REDACTED] in Poland. ADC then transfers the final reader kits to [REDACTED].

c. ADC personnel

80. I have further been asked to assume that ADC-employed personnel are involved in directing the manufacture, import, and sale of FSL products that are sold in Europe, including Germany; and that ADC employees hold high level roles in the Global Sourcing and Supply Chain Organizations, involved in facilitating the flow of products from manufacture to sale.

4. Basis for opinion

81. Based on the applicable precedent and the product flow information described above which, again, I have been asked to assume as true, it is my opinion that

the manufacture, import (where applicable) and first sale in the EU of FSL products to be sold in Germany are valid exercises of ADC's rights under the SLA.

a. Readers

82. It is my opinion that the manufacture of the finished reader kits is a valid exercise of ADC's "have made" rights. The readers are manufactured [REDACTED] for ADC under an agreement with ADC, in accordance with purchase orders issued by ADC, and based on design specifications provided by ADC.

83. Further, ADC takes title to the final reader kits [REDACTED]. Under the terms of that transfer, ADC takes title at the seller's place, *i.e.*, in Poland, which is in the EU. ADC then sells the product on to [REDACTED] in Germany, which in turn sells it to Abbott GmbH for distribution in Germany.

84. In this scenario, the first sale of the final product in the EU is effected directly by ADC, which would be an exercise of its sale rights under ¶ C.2 of the SLA.

b. On-body units

85. Although ADC itself does not manufacture, import or sell within the EU the on-body units that ultimately are sold in Germany, it is my opinion based on review of all the circumstances, that those activities constitute a valid exercise of ADC's rights under the SLA.

86. As an initial matter, ADC employees are involved in coordinating the flow of FSL on-body units from manufacture to distribution.

87. Further, ADC owns all of the IP and know-how relating to the FSL products. As such, the on-body units are assembled by [REDACTED] according to know-how owned by ADC.

88. Under these circumstances, although ADC does not itself take title to the on-body units after their assembly by the TPMs, the manufacture, import and sale of FSL products is done by third-party service providers and ADC affiliates according to instructions from ADC employees. As the U.S. courts have held, there are no “special requirements on licensees to exercise their have made rights.” *Carnegie Mellon Univ.*, 2020 WL 5592990, at *4. Further, the use of foreign affiliates to conduct these transactions is merely a “modern industrial reality” directed by laws of commerce, rather than to undermine the provisions of the SLA.

89. In this way, the arrangements with the TPMs [REDACTED] are similar to those described in the caselaw, such as in *Cyrix* and *LaserDynamics*, where a third party is engaged to manufacture a licensed product to meet the licensee’s obligations to customers under its “have made” rights. That the license in the SLA is not sub-licensable does not alter this conclusion, because, as the U.S. courts have held, “a right to have made is not a sublicense,” and “the contractor who makes for the licensee does not receive a sublicense from the licensee.” *Carnegie Mellon*, 2020 WL 5592990, at *4 (quoting *CoreBrace LLC v. Star Seismic LLC*, 566 F.3d 1069, 1073 (Fed. Cir. 2009)).

90. Nor do any of the exceptions to the valid exercise of “have made” rights apply. For example, as noted, the finished on-body units made by [REDACTED] are not “off-the-shelf” components, but rather are made according to the FSL know-how owned by ADC. There is nothing in the SLA indicating that “have made” rights do not to apply in these circumstances. To the contrary, the grant of “have made” rights under the license provision is explicit. (SLA, ¶ C.2.)

91. It is also my opinion that the import of the FSL products (where applicable) into the European market is done as a valid exercise of ADC's "have imported" right under the SLA.

92. The product being imported into the EU is manufactured [REDACTED] in accordance with instructions from ADC employees. The facts I have been asked to assume as accurate indicate that ADC employees are responsible for shipping, distribution, warehousing and other associated functions once the FSL products are manufactured.

93. The product flow structure adopted by Abbott for import into, and sale in, the European market of ADC's FSL products, including Abbott's use of locally-based affiliates to import and distribute its FSL products in Europe (including in Germany), "reflect[s] typical on-time delivery logistics of modern industrial reality," as with the "have made" arrangements endorsed by the U.S. courts. *See LaserDynamics, Inc. v. Quanta Comput., Inc.*, 694 F.3d 51, 72 (Fed. Cir. 2012); *Carnegie Mellon*, 2020 WL 5592990, at *4.

94. Nor do the exceptions to "have made" rights apply to the exercise of ADC's "have imported" rights. The FSL products being imported into Europe are not "off-the-shelf" components. They appear to meet the definition of ADC Products made for ADC under ¶ A.3 of the SLA, which also contemplated that ADC would be permitted to have the FSL products imported into Europe for it under the Agreement. I have seen no indication that the product flow structure was adopted to circumvent the SLA. Under the SLA, ADC would be permitted to import the FSL products into, and sell them in Europe, including Germany. That the products are instead imported into and distributed in the European market by ADC's affiliates is a matter of form, not substance.

95. In summary then, it is my opinion that the manufacture of FSL on-body units, and their subsequent import into the European market for sale in Europe, including Germany, is a valid exercise of ADC's "have made" and "have imported rights" under the SLA.

Date: October 7, 2021



Hon. Timothy K. Lewis

Exhibit A

Hon. Timothy K. Lewis
Schnader Harrison Segal & Lewis LLP
BIOGRAPHICAL STATEMENT

Former federal judge Timothy K. Lewis is Co-Chair of the ADR Practice Group and the former Co-Chair of the Appellate Practice Group at the law firm of Schnader Harrison Segal & Lewis, where he also serves as a mediator, arbitrator, settlement counselor, and as an appellate practitioner.

Before entering private practice, Judge Lewis served on the United States Court of Appeals for the Third Circuit. He had served as a United States District Court Judge before President George H. W. Bush elevated him to the Court of Appeals in 1992. At the time of both appointments he was the youngest federal judge in the United States. Prior to his appointment to the federal bench, Judge Lewis served as an Assistant United States Attorney for the Western District of Pennsylvania, and as an Assistant District Attorney in Allegheny County, Pennsylvania. Since leaving the bench, in addition to his ADR and appellate practices, he provides strategic counseling and conducts moot courts in various federal appellate matters throughout the country, and has served on the faculty of many Continuing Legal Education programs focusing upon appellate practice and procedure, mediation, arbitration, and general commercial litigation. He has been a guest speaker at events sponsored by, among others, the ABA, the International Institute for Conflict Prevention and Resolution (CPR), the American Arbitration Association, and the Pennsylvania, New York, California, Texas, Maryland, and District of Columbia Bars.

Judge Lewis is a member of the American Law Institute, a Fellow of the American Academy of Appellate Lawyers and the College of Commercial Arbitrators, and serves on the Pennsylvania Interbranch Commission on Gender, Racial and Ethnic Fairness. He is a former member of the Board of Directors of the American Arbitration Association, where he also served on the Executive Committee and chaired the Committee on Diversity in ADR. Judge Lewis also served on the Board of Directors of the CPR Institute and is a member of its National Panel of Distinguished Neutrals. He is a founding member of the Bernard G. Segal Institute for Appellate Advocacy LLC, and serves on its Board of Advisors. He is also a member of the Board of Advisors of the Georgetown Supreme Court Institute, and the Duquesne Law School Dean's Advisory Board. Judge Lewis is a former member of the Advisory Board of the Public Interest Law Center of Philadelphia. He is also a former member of the Board of Directors of the National Jazz Museum in Harlem.

Judge Lewis taught Advocacy and Adjudication as an adjunct professor at the University of Pittsburgh School of Law and is a former member of the Visiting Committee of the University of Chicago School of Law. He served as a Board member of The Peter Jennings Project for Journalists and the Constitution at the National Constitution Center in Philadelphia, and is a former member of the Edward Coke Appellate Inn of Court in Washington, DC.

Judge Lewis was a member of the Practitioners Reading Group for the nominations of John Roberts as Chief Justice of the United States, and Sonia Sotomayor and Elena Kagan as Associate Justices of the U.S. Supreme Court. This group of 13 lawyers from across the United States evaluated the writings of the nominees and made recommendations later presented to the Senate Judiciary Committee.

Judge Lewis has also trained Department of Justice attorneys in mediation at the National Advocacy Center in Columbia, South Carolina, and has served as an Instructor in Trial Advocacy at the Attorney General's Advocacy Institute. He has served as a commencement speaker, a guest lecturer, and a moot court judge at various law schools, including the University of Pittsburgh, the Georgetown Law Center, Duquesne, Temple, Harvard, and the University of Pennsylvania. He is a former member of the House of Delegates of the Pennsylvania Bar Association, and has served on various Allegheny County Bar Association committees. In December 2002, Judge Lewis served as the United States representative on an international faculty of judges and mediators during a U.S. AID-sponsored Mediation Roundtable in the Republic of Croatia. In February 2008, Judge Lewis served as a Delegate to the U.S.-Russian Roundtable Conference on International Peace in Moscow, which was an outgrowth of the G-8 Summit, and delivered the opening statement on behalf of the U.S. Delegation. Judge Lewis has also served as Co-Chair, along with former U.S. Transportation Secretary William T. Coleman, of the Just the Beginning Foundation Conference in Washington, D.C., in 2008, which is the biennial three-day conference of Article III minority judges.

Judge Lewis is a member of the National Board of Directors of the American Constitution Society (ACS) and The Constitution Project, and a Co-Chair of the National Committee on the Right to Counsel. This Committee includes leaders from across the political and ideological spectrums, and in 2009 published a Report addressing the state of indigent defense in the United States with recommendations to Congress and state legislatures for improvement. During the fall of 2003, Judge Lewis chaired and moderated a series of national town meetings and congressional-style hearings called by Amnesty International on the subject of *Racial Profiling, Pre- and Post-9/11*. He has filed many *amicus* briefs in the United States Supreme Court in cases ranging from Guantanamo detainees to the death penalty to bankruptcy matters to judicial ethics. In 2014, he advised Pennsylvania Governor Tom Wolfe on the constitutionality of imposing a moratorium on the death penalty in Pennsylvania, which was adopted and implemented by the Governor and later sustained by the Pennsylvania Supreme Court. In 2016, Judge Lewis testified before Senate Democrats in support of the then-pending nomination of Judge Merrick Garland to the United States Supreme Court and, with then-Vice President Joe Biden, delivered the President's Weekly Address to the Nation in further support of Judge Garland's nomination.

Hon. Timothy K. Lewis
Schnader Harrison Segal & Lewis LLP

Judge Lewis has received many awards and honors, both as a judge and as an attorney, including:

Pennsylvania Bar Association — Minority Bar Committee Award of Achievement;

Outstanding Achievement Award, Duquesne University School of Law;

Distinguished Alumni Award, The Kiski School;

Athletic Hall of Fame, The Kiski School;

Best Lawyers "2015 Lawyer of the Year" in arbitration for Washington, D.C.;

Best Lawyers "2021 Lawyer of the Year" in arbitration for Pittsburgh, PA;

Recognition in *The Best Lawyers in America* in the areas of Administrative/Regulatory Law, Appellate Law, Arbitration, Commercial Litigation, and Mediation (2010-2021);

Recognition as a 2013 "Washington D.C. Super Lawyer for Alternative Dispute Resolution";

Recognition by the editors of *The National Law Journal* and *The Legal Times* as one of the publication's 2010 "Champions & Visionaries," honoring attorneys who have gone the extra mile to enhance the business of law and ensure justice is done;

Recognition as one of "Lawdragon 500 Leading Judges in America" by *Lawdragon* magazine;

Outstanding Director Award, given by the American Arbitration Association to a member of the organization's Board of Directors who has distinguished him or herself through singular and outstanding efforts in furthering the Association's mission of service and education in the field of conflict management;

Selected as one of *The Legal Intelligencer's* "Diverse Attorneys of the Year" for 2015;

"Leadership Excellence Award" by the National Diversity Council;

Pennsylvania Human Relations Commission Mediation Services Award for furthering education equity in Pennsylvania;

The Association for Conflict Diversity and Equity Award.

Judge Lewis's community activities include:

The Kiski School, Board of Trustees;

Imani Christian Academy, Governing Board of Directors;

The Boule (national post-baccalaureate fraternity of professional black men);

Boy Scouts of America, Southwestern Pennsylvania Region, Board of Directors (former member);

Pittsburgh Children's Museum Board of Directors (former member).

Judge Lewis graduated from Tufts University with a Bachelor of Arts in Political Science in 1976. He received his law degree from Duquesne University in 1980.

**Hon. Timothy K. Lewis
Schnader Harrison Segal & Lewis LLP**

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PRELIMINARY STATEMENT¹

Plaintiff DexCom, Inc. (“DexCom”) opposes the Motion to Transfer filed by Defendants Abbott Diabetes Care, Inc. (“ADC Inc.”) and Abbott Diabetes Care Sales Corp (“ADC Sales”) (collectively, “Abbott”). Defendants’ motion relies on a forum selection clause in a 2014 Settlement and License Agreement (ECF 35-8; the “SLA”), which—among other things—granted Abbott and DexCom licenses to certain of each other’s patents. This tactic, which Abbott raised for the first time months into this case and has inconsistently asserted in other cases involving DexCom, highlights Abbott’s clear preference to litigate anywhere but this District. Yet, although courts often grant transfer in patent infringement cases if the movant raises a “non-frivolous” argument that a forum selection clause governs the dispute, Abbott fails to clear even that low bar. Abbott’s defense is frivolous.

Abbott relies on certain SLA provisions to argue that the Patents-in-Suit are [REDACTED] of one of DexCom's pre-2005 patents or patent applications. The terms of the SLA make clear that "[REDACTED]

Abbott submits that the proper U.S. legal standard is obviousness under 35 U.S.C. § 103, arguing that DexCom's pre-2005 patent applications are prior art that render certain claims of the Patents-in-Suit obvious. But that cannot be right for at least two reasons. First, DexCom can neither hold valid patent claims in or grant licenses to claimed inventions that are obvious under 35 U.S.C. § 103; such inventions are not patentable, obviating the need for any license. Moreover, Abbott's application of section 103 is incorrect as a matter of law insofar as it relies on DexCom's patent applications that were not published when DexCom invented the claims of the Patents-in-Suit; such applications are *not*

¹ Internal quotations and citations are omitted, and emphases supplied, unless noted. “Ex. _” refers to the exhibits to the concurrently-filed Declaration of Alex Zuckerman. “Mot.” refers to Abbott’s Motion to Transfer (ECF 35).

eligible prior art for purposes of showing section 103 obviousness. To determine whether a claim is licensed, Abbott thus purports to apply a standard that would either grant a license to DexCom's claims only when those claims are invalid, or violate the standard's explicit requirements. That is the epitome of frivolity. Finally, Abbott's license defense is also nonsensical in that it suggests that Abbott may claim a license to all of DexCom's past, present, and future patents without limitation, despite the [REDACTED]

[REDACTED] That contradiction is one of many reasons why this Court need not interpret the SLA or apply it to the facts of this case. Abbott's license defense is frivolous, and the forum selection clause does not apply.

Abbott's Section 1404 argument also fails. Neither alternative venue is clearly more convenient given: [REDACTED]

[REDACTED] there is no evidence that other witnesses will not travel here; and the speed to trial in this District relative to the transferee districts. Abbott's Motion to Transfer should be denied.

BACKGROUND

A. The Settlement and License Agreement

On July 2, 2014, DexCom and Abbott resolved three consolidated patent infringement actions (the "Delaware Litigation") [REDACTED] through which each obtained licenses to certain of the other's patent claims. [REDACTED]

DexCom licensed to Abbott certain patent claims on a claim-by-claim basis:

"(a) All worldwide patents and patent applications . . . that DexCom owns [with] . . . an actual filing date before January 1, 2005 [**"Pre-2005 Patents or Applications"**] . . . ;

"(b) All worldwide patents that DexCom owns or has the right to enforce . . . that (i) have issued as of the Effective Date and that, as of May 15, 2014 claimed, or at any time thereafter claim, priority (in whole or in part) to any of [the Pre-2005 Patents or Applications], or (ii) issue in the future from any patent applications currently pending or

subsequently filed . . . that . . . claim . . . priority . . . to any [Pre-2005 Patent or Application];

“(c) A claim in a continuation, continuation-in-part, divisional or any other worldwide patent claiming priority to a patent captured in subsection (b), but not claiming priority to

[REDACTED] if . .

. either (i) the claim is fully supported and enabled in the manner required under 35 U.S.C.

§ [REDACTED]

[REDACTED]

[REDACTED]

(SLA ¶ A.13.) DexCom further agreed that it “[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Abbott’s remedy in the event DexCom breached [REDACTED],

was that such claims [REDACTED] (*Id.*) [REDACTED]

[REDACTED]

[REDACTED],” are the heart of the dispute here.²

B. Abbott’s Activities in this District

ADC Inc. carries out its business [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

² [REDACTED]

[REDACTED]

C. Procedural Background

Both DexCom and Abbott have each obtained numerous patents since executing the SLA. Once the Covenant Period expired, those developments spawned new litigation. On June 30, 2021, DexCom filed this case, asserting five patents issued to DexCom in 2020 and 2021: U.S. Patent Nos. 11,000,213 (“213 Patent”), 10,980,452 (“452 Patent”), 10,702,215 (“215 Patent”), 10,702,193 (“193 Patent”), and 10,993,642 (“642 Patent”) (collectively, the “Patents-in-Suit”). (ECF 19 ¶ 2.) DexCom also filed patent infringement complaints against Abbott and its affiliates in Germany on July 1 (“German Litigation”). One day later, Abbott sued DexCom in the District of Delaware for patent infringement, asserting twelve patents. (*See* Ex. 4 (“Delaware Action”).) Two weeks later, Abbott sued DexCom in the United Kingdom seeking revocation of the patents that are counterparts to those DexCom is asserting in Germany (“UK Litigation”). (*See* Ex. 5, UK Compl.) Had Abbott believed that it held a license to DexCom’s patent claims, it could have promptly argued as much in either Delaware or the UK, either be seeking a declaratory judgment in the former, or by raising the SLA in either its complaint or response to DexCom’s counterclaim in the latter. Instead, Abbott said nothing about the SLA for months.

Abbott’s purported license defense finally took shape on September 20, 2021, when it argued for the first time in the present Motion that the SLA applied to claims of the Patents-in-Suit. Specifically, Abbott now argues that “[e]very patent claim DexCom is asserting here falls within the scope of its license” because “DexCom’s Licensed Patents” [REDACTED]

[REDACTED] Abbott attached lengthy claim charts that purport to show how an asserted claim of each of the Patents-in-Suit is [REDACTED]. (Mot. at 7; Mot. Exs. H, I, M, N, & O.) [REDACTED]

[REDACTED] (i) U.S. Prov. No. 60/614,764, a provisional patent application filed on September 30, 2004 (Mot. Ex. D; “764 Prov.”); (ii) WO 2005/010518, an international patent application published on March 2, 2005 (Mot. Ex. E; “518 Pub.”); (iii) WO 2005/057168, an international patent application published on June 23, 2005 (Mot. Ex. F; “168 Pub.”); and (iv) U.S. Prov. No. 60/614,683, a provisional patent application filed on September 30, 2004 (Mot. Ex. G; “683 Prov.”).³

Five months after litigation began in this District, Germany, the United Kingdom, and Delaware, and over two months after filing this Motion, Abbott brought a second action in Delaware alleging breach of the SLA and seeking, *inter alia*, a declaratory judgment “of non-infringement due to license” with respect to each of the Patents-in-Suit here, as well as those at issue in Europe. (*See* Ex. 6 (“Second Delaware Action”).) The Second Delaware Action, which, again, Abbott could have brought months earlier, rests on the same theory as the Motion to Transfer: the Patents-in-Suit are licensed under the SLA.

LEGAL STANDARD

28 U.S.C. §1404(a) provides that “[f]or the convenience of parties and witnesses, in the interest of justice, a district court may transfer any civil action to any other district or division where it might have been brought or to any district or division to which all parties have consented.” The plaintiff’s choice of forum should be respected unless the defendant can demonstrate good cause for transfer. *See In re Volkswagen, Inc.*, 545 F.3d 304, 314 (5th Cir. 2008) (“*Volkswagen II*”). The burden the moving party “must carry is not that the alternative venue is more convenient,

³ Similarly, Abbott argued that all of DexCom’s claims in the German Litigation are “[REDACTED]” To support that claim, Abbott relied on the declaration of the Honorable Timothy K. Lewis, a purported expert on U.S. law, who advised the German Court to refer to [REDACTED] (Ex. 8, Lewis Decl. ¶ 43.) Even though the German Litigation and the UK revocation action involve the same patents, Abbott has never raised its [REDACTED] in the UK proceeding.

but that it is clearly more convenient.” *TMT Systems, Inc. v. Medtronic, Inc., et al.*, 2021 WL 5316406, *2 (W.D. Tex. Oct. 19, 2021) (citing *Volkswagen II*, 545 F.3d at 314 n.10).

The first question under §1404(a) is whether the action “‘might have been brought’ in the destination venue.” *Volkswagen II*, 545 F.3d at 312 (quoting § 1404 (a)). If so, courts consider whether public and private interest factors (none individually dispositive) show that transfer is convenient. The private concerns include: “(1) the relative ease of access to sources of proof; (2) the availability of compulsory process to secure the attendance of witnesses; (3) the cost of attendance for willing witnesses; and (4) all other practical problems that make trial of a case easy, expeditious and inexpensive.” *In re Volkswagen AG*, 371 F.3d 201, 203 (5th Cir. 2004) (“*Volkswagen P*”). The public concerns are: (1) “administrative difficulties flowing from court congestion;” (2) “local interest” in the subject matter; (3) the court’s “familiarity . . . with the [governing] law; and (4) the avoidance of unnecessary problems of conflict of laws or the application of foreign law.” *Id.* If there is a binding and applicable forum selection clause, courts only analyze the public interest factors, and “should not consider the . . . private interests.” *Atl. Marine Constr. Co., Inc. v. U.S. Dist. Court for the W. Dist. Of Tex.*, 571 U.S. 49, 62–65 (2013).

A forum selection clause in a patent licensing agreement warrants transfer only if there is a “non-frivolous dispute regarding the scope of [the] patent license.” *Gen. Protecht Grp., Inc. v. Leviton Mfg. Co.*, 651 F.3d 1355, 1359 (Fed. Cir. 2011). “[A] bare allegation that [a license] provides a defense to the claims in suit fails to meet this standard and will not trigger a forum selection clause.” *Id.* Rather, a defendant seeking transfer based on a license defense must present “colorable, factually specific arguments as to why” the asserted patents are covered by the license. *Uniloc USA, Inc. v. Cisco Sys., Inc.*, 2017 WL 959856, at *4 (E.D. Tex. Mar. 13, 2017). A license defense is non-frivolous if the court must consider the particular context to determine

whether the “patent infringement suits are at least connected” to the licensing agreement. *Rovi Guides, Inc. v. Comcast Corp.*, 2016 WL 6217201, at *4 (E.D. Tex. Oct. 25, 2016).

ARGUMENT

I. ABBOTT’S LICENSE DEFENSE BASED ON THE SLA IS FRIVOLOUS

Abbott’s asserted license defense is contrary to law on its face and amounts to the very type of “bare allegation” that does not trigger a forum selection clause. Abbott argues that this case must be transferred under the SLA’s forum selection clause because each of the Patents-in-Suit was [REDACTED] of subject matter “disclosed in the prior art” in one of DexCom’s pre-2005 patents and applications, which “would have been obvious to a person of ordinary skill in the art (‘POSITA’).” (Mot. at 7-10.) Abbott thus refers to the standard for obviousness set forth in 35 U.S.C. § 103. (See Mot. at 8 (grounds for invalidity “under § 103”).) Even if that standard were correct to determine whether a claim of the Patents-in-Suit is “[REDACTED] [REDACTED] [REDACTED]—which DexCom does not concede—Abbott fails to apply it correctly. Its license defense based on [REDACTED] is thus frivolous.

A. Abbott’s Asserted License Defense Is Not Based on a Reasonable Interpretation of the SLA or a Valid U.S. Legal Standard.

Abbott relies on [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

⁴ Three indisputable points follow from this: (1) [REDACTED]
[REDACTED]

⁴ Abbott’s claim charts only cover five of DexCom’s asserted claims (one for each patent), although there are now 60 asserted claims, and DexCom no longer asserts Claim 19 of the ’215 Patent, covered by Abbott’s Exhibit M.

Only two U.S. standards remotely suggested by [REDACTED] language meet these criteria: obviousness-type double patenting and obviousness under 35 U.S.C. § 103. Abbott does not purport to apply the former and fails to apply the latter correctly.

B. Abbott Does Not Even Contend That the [REDACTED] of the SLA Refer to Obviousness-Type Double Patenting.

One reading of the [REDACTED] refers to the doctrine of obviousness-type double patenting, which prohibits the unjustified extension of a patent term via a second application by “prevent[ing] a patentee from obtaining a patent that is an *obvious variation* of claims in a prior patent.” *Hydro-Quebec v. Valence Tech., Inc.*, 2011 WL 13175075, at *3 (W.D. Tex. Nov. 1, 2011) (emphasis added). As the Manual of Patent Examining Procedure (“MPEP”) explains, any obviousness-type double patenting analysis must include:

(A) The differences between the inventions defined by the conflicting claims — a claim in the patent compared to a claim in the application; and (B) The reasons why a person of ordinary skill in the art would conclude that the invention defined in the claim at issue would have been an *obvious variation* of the invention defined in a claim in the patent.

MPEP § 804 ¶ 8.34.⁵ Abbott does not address or apply that standard for [REDACTED]

Indeed, Abbott refers to the [REDACTED] deleting the key term [REDACTED] altogether.⁶

⁵ There are foreign equivalents to obviousness-type double patenting. *See, e.g.*, Patents Act 1977 § 18(5) (UK) (“Where two or more applications for a patent for the same invention having the same priority date are filed by the same applicant . . . the comptroller may on that ground refuse to grant a patent [to] more than one of the applications.”)

⁶ [REDACTED] *Abbvie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr.*, where the Court explained that obviousness-type double patenting invalidates a “later expiring patent [if it] is merely an *obvious variation* of an invention disclosed and claimed in [an earlier] patent.” 764 F.3d 1366, 1379 (Fed. Cir. 2014).

C. Abbott’s Arguments That the Patents-in-Suit Are Obvious Under 35 U.S.C. § 103 Are Contrary to Law.

Abbott asserts that certain claims of the Patents-in-Suit are [REDACTED] because they “would have been obvious to a person of ordinary skill in the art (‘POSITA’)” under section 103. (*See* Mot. at 8-10.) Section 103 precludes patentability if, in light of prior art, “the claimed invention as a whole would have been obvious before [its] effective filing date . . . to a person having ordinary skill in the art to which the claimed invention pertains.” But a license to claims that are obvious in light of prior art is both incoherent and contrary to public policy: obvious inventions are not patentable and, thus, not licensable. *See Kimble v. Marvel Ent., LLC*, 576 U.S. 446, 451 (2015) (“[P]atent laws . . . preclude measures that restrict free access to . . . unpatentable[] inventions.”); *cf. Adm’rs of Tulane Educ. Fund v. Debio Holding, S.A.*, 177 F. Supp. 2d 545, 549 (E.D. La. 2001) (after expiration, patentee’s rights to license its patents “become public property”) If Abbott’s license defense depends on such a framework, it is surely frivolous.⁷

Even if DexCom could license inventions deemed obvious under section 103, Abbott’s arguments are frivolous for their reliance on prior art references that cannot establish obviousness. In this case, all the Patents-in-Suit have an effective filing date before March 16, 2013 (the effective date of the America Invents Act (“AIA”)). (*See* Ex. 9, DexCom’s Amended Infringement Contentions (“AIC”) at 4.) Accordingly, Abbott may only cite the applications in its brief as section 103 prior art if the applications were valid prior art under the pre-AIA standards: namely, if they were “described in a printed publication” before the claimed invention date under pre-AIA 35 U.S.C. § 102(a), or, in the case of unpublished prior patent applications, under pre-AIA 35 U.S.C. § 102(e) if the claimed invention was: (i) described in either “(1) an application for patent

⁷ By contrast, if the “obvious variant” provisions refer to double patenting, it makes sense for the licensed patents to include post-2005 applications that are merely an “extension of [an already licensed] patent term beyond its defined statutory period.” *VideoShare, LLC v. Google, LLC*, 2021 WL 4712692, at *5 (W.D. Tex. Oct. 8, 2021).

. . . *by another* filed . . . before the invention by the applicant for patent or (2) a patent granted on an application for patent *by another* . . . before the invention by the applicant for patent,” Pre-AIA 35 U.S.C. § 102(e), *and* (ii) not “at the time the claimed invention was made, [or] owned by the same person....” Pre-AIA 35 U.S.C § 103(c)(1). For example, a pre-AIA patent claim is not “obvious” if the only asserted basis for obviousness is an application owned by the same person or entity that was unpublished on the invention date of the pre-AIA claim. *See* MPEP § 2146.01 (pre-AIA 35 U.S.C. § 103(c)(1) disqualifies prior art of same inventor); MPEP § 2128 (“printed publication” is prior art under pre-AIA 102(a) only if “accessible to . . . the public”).

Abbott wholly fails to prove obviousness under 35 U.S.C. §§ 102 and 103. As an initial matter, Abbott does not even try to offer a proper basis for relying on the various DexCom applications cited in its Motion (e.g., Mot. Exs. D-G) in a section 103 analysis. *See, e.g., Uniloc 2017 LLC v. Cisco Sys., Inc.*, 2019 WL 4451329, at *2 (E.D. Tex. Sept. 16, 2019) (agreeing that “license defense is frivolous . . . [if defendant] has not logically connected the dots” with appropriate documents in support of its argument). For example, Abbott makes no attempt to show that any of the Pre-2005 Patents And Applications it relies on: (a) had been published by the relevant date of any of the five Patents-in-Suit; (b) is an application by another filed in the United States before the invention of any claim of any of the Patents-in-Suit and was not, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person; or (c) is otherwise available for use in a proper section 103 analysis. Abbott merely assumes—and effectively asks this Court to assume—that the cited Pre-2005 Patents And Applications are usable for that purpose. But conclusory allegations, unsupported by “factually specific arguments,” are inadequate. *Uniloc*, 2017 WL 959856, at *4 (third party license defense

non-frivolous where license expressly “applied to any and all third parties”).⁸

This failure is not without consequence. Abbott’s ██████████ analysis improperly relies on multiple DexCom patent applications that were not published as of their respective Patent-in-Suit’s invention date, and therefore do not qualify as prior art under section 103.

Patent-in-Suit	Priority Date of Asserted Claim (Ex. 9 at 4.)	Abbott-Cited DexCom Application	Defects in Abbott Analysis
'642 Patent	June 21, 2005	764 Prov.	The 764 Prov. was not published before June 21, 2005. (See Ex. 10, US2006/0019327A1, at A1 (published Jan. 26, 2006).)
'193 Patent	April 15, 2005	168 Pub.	The 168 Pub. was published June 23, 2005, after April 15, 2005. (Mot. Ex. F at 1.)
'213 Patent	March 10, 2005	764 Prov.	The 764 Prov. was not published before March 10, 2005. (See Ex. 10, US2006/0019327A1 (published Jan. 26, 2006).)

Abbott’s ██████████ arguments are also untethered from the clear temporal requirement of section 103 that assesses whether the subject matter of a claimed invention “would have been obvious” in light of available prior art “*at the time the invention was made* to a [POSITA] to which the claimed invention pertains.” 35 U.S.C. § 103. Instead, for the '215 Patent, Abbott argues, ██████████

(Mot. Ex. M at 7.) Similarly for the '642 Patent, Abbott contends the subject matter ██████████

██████████ (Mot. Ex. I at 12.)

None of these dates is either on or before “the time the invention was made”—which was October

⁸ Nor may Abbott cure these infirmities on reply. See *Mission Toxicology, LLC, et al. v. UnitedHealthcare Ins. Co.* 499 F.Supp.3d 350, 359 (W.D. Tex. 2020) (“[A]rguments raised for the first time in a reply brief are . . . waived.”).

30, 2012 for the '215 Patent and June 21, 2005 for the '642 Patent. (Ex. 9, AIC at 4.) [REDACTED]

[REDACTED]

[REDACTED]⁹

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Without an argument that any of DexCom's asserted claims are [REDACTED]—and given the lack of a proper Section 103 analysis for the majority of the Patents-in-Suit—Abbott fails to present a non-frivolous license defense.¹⁰

II. NEITHER DELAWARE NOR THE NORTHERN DISTRICT OF CALIFORNIA IS A MORE CONVENIENT FORUM

Defendants have failed to meet their burden to show that the Northern District of California (N.D. Cal.) is a more convenient venue, and their motion also should be denied to that extent.

A. The Northern District of California Is Not a Clearly More Convenient Venue.

1. The private interest factors weigh against transfer to N.D. Cal.

Convenience for potential witnesses. Defendants allege that N.D. Cal. is more convenient because of its proximity to Abbott's headquarters. (Mot. at 12.) But "[t]he availability and convenience of party-witnesses"—even those Abbott speculates may testify—"is generally

⁹ Nor can Abbott credibly argue—as it attempts to do—that claims of the Patents-in-Suit are licensed [REDACTED]

[REDACTED]

¹⁰ [REDACTED]

[REDACTED]

The obviousness arguments fail for the reasons set forth above, and Abbott does not make a § 112 argument.

insignificant” where transfer “would only shift the inconvenience from [defendant] to [plaintiff].” *Quicksilver, Inc. v. Acad. Corp.*, 1998 WL 874929, at *2 (N.D. Tex. Dec. 3, 1998). [REDACTED]

[REDACTED] this factor weighs against transfer.¹¹

Availability of Compulsory Process. Abbott argues that this factor supports transfer because there are former ADC Inc. employees closer to N.D. Cal. who may be called as witnesses. First, this factor only favors transfer when “more *non-party* witnesses reside within the transferee venue than reside in the transferor venue.” *In re Apple*, 581 F. App’x 886, 889 (Fed. Cir. 2014). That is not the case here: [REDACTED]

[REDACTED] For that reason, Abbotts’ reliance on *In re Nintendo* is unavailing: there, no third-party witnesses lived in Texas. 589 F.3d 1194, at 1199 (Fed Cir. 2008). Second, instead of addressing those relevant non-party witnesses, Abbott urges transfer based on the location of “former ADC employees [who] . . . contributed [to] . . . ADC’s accused technology.” (Mot. at 13.) But those purported inventors, whom Abbott *might* put at issue, are irrelevant to the 1404 analysis unless they will not appear. The witness availability factor merits little weight since Abbott has not “alleged or shown any witness’s unwillingness” *Cloud of Change, LLC v. NCR Corp.*, 2020 WL 6439178, at *4 (W.D. Tex. Mar. 17, 2020).

Location of sources of proof. Acts of infringement, which include “mak[ing], us[ing], sell[ing], or offer[ing] to sell” an infringing product, *see* 35 U.S.C. § 271(a), occur both a [REDACTED]

[REDACTED] Where sources “are maintained locally” in the district, this

¹¹ Abbott’s claim that N.D. Cal. is a more convenient forum for DexCom is irrelevant. (Mot. at 12). DexCom’s witnesses will appear here. *See Coleman v. Trican Well Service, L.P.*, 89 F. Supp. 3d 876, 884 (W.D. Tex. 2015) (party employees “presumed to appear willingly.”). DexCom has the “ability to determine what is convenient for itself.” *See, e.g., ACQIS LLC v. MiTAC Computing Tech. Corp.*, 2021 WL 4805431, at *3 (W.D. Tex. Oct. 14, 2021).

factor weighs against transfer. *SSL Servs., LLC v. Cisco Sys., Inc.*, 2016 WL 727673, at *2 (E.D. Tex. Feb. 24, 2016). Defendants nevertheless claim that N.D. Cal. is more appropriate [REDACTED]

[REDACTED]. But that activity is not the only actionable type of infringement; anyone who “makes, uses, sells, or offers to sell” may be liable under 35 U.S.C. § 271(a).¹² [REDACTED]

[REDACTED] this factor weighs against transfer.¹³

2. The public interest factors weigh against transfer to N.D. Cal.

Local Interest. Abbott argues that there is no local interest because DexCom has minimal contact with this District. (Mot. at 8.) But the plaintiff’s connection to the forum is irrelevant; the local interest factor turns on “significant connections between [the transferor] forum and *the events that gave rise to a suit.*” *In re Apple*, 979 F.3d 1332, 1344 (Fed. Cir. 2020) (emphasis in original); *see also Seven Networks, LLC v. Google, LLC*, 315 F. Supp. 3d 933, 942 (E.D. Tex. 2018) (venue proper where infringing product made). [REDACTED]

[REDACTED]

[REDACTED] As this Court held in *NCS Multistage v. TCO AS*, 2021 WL 2187954 (W.D. Tex. May 28, 2021), the local interest factor weighs against transfer when there are “individuals who work . . .

¹² Defendants’ cited authority, *XY, LLC v. Trans Ova Genetic, LC*, , 2017 WL 5505340 (W.D. Tex. Apr. 5, 2017), underscores this fact: the “trier of fact ought to be as close as possible to the milieu of the infringing device and the hub of activity centered around its *production.*” *Id.* at *13. For *Libre 3*, that is the Flex Facility.

¹³ This Court has recognized that “there is no difference in the relative ease of access to sources of proof” in modern patent litigation, where “documents are easily accessible electronically.” *Uniloc 2017 LLC v. Apple Inc.*, 2020 WL 3415880, at *9 (W.D. Tex. June 22, 2020). Given their exchanging electronic discovery, the parties are clearly capable of making sources of proof available in this District. Furthermore, [REDACTED] both are closer to this District than to N.D. Cal. [REDACTED]

for [parties]” and a strong customer base in this District. *Id.* at *7. Both are true here: [REDACTED]

Remaining Public Interest Factors. Abbott claims that the court congestion factor is neutral. (Mot. at 14). But the relevant question is speed to trial, not the number of cases per judge. *In re Genentech*, 536 F.3d 1338, 1347 (Fed. Cir. 2009). This Court recently found that patent cases languish for an extra year in N.D. Cal. *See Exp. Mobile, Inc. v. Atlassian Corp. PLC*, 2021 WL 3355375, at *10 (W.D. Tex. Aug. 2, 2021) (time to trial in N.D. Cal. “could be much longer than twelve months.”). Abbott concedes that this forum is as capable as any other to avoid conflicts of law and to apply patent law. Thus, none of the public interest factors supports transfer.

B. The Public Interest Factors Do Not Support Transfer to Delaware.

For the reasons set forth above, transfer to Delaware is not warranted under the SLA. The public interest factors also weigh against transfer to Delaware, a forum nearly twice as far (~2900 miles) from Abbott’s Alameda headquarters as this District (~1485 miles):

- **Administrative Difficulties:** Abbott concedes that the median time to trial is nearly ten months longer in Delaware. (Mot. at 14.) That lag is similar to the interval this Court found to weigh against transfer in *FCX Solar v. LLC v. FTC Solar, Inc.*, 2021 WL 4953912, at *8 (W.D. Tex. Oct. 25, 2021) (11.5 months).
- **Local Interest:** A party’s state of incorporation is insufficient to establish a local interest in the outcome. Rather, “[a] local interest is demonstrated by a relevant factual connection between the events and the venue.” *Kajeet, Inc. v. Trend Micro, Inc.*, 2022 WL 126490, at *7 (W.D. Tex. Jan. 12, 2022) (internal citation omitted). Abbott argues no such connection to Delaware. This factor weighs against transfer.
- **Familiarity with Law & Avoidance of Conflict:** These factors are neutral where, as here, the “case arises from federal patent law.” *Ravgen, Inc. v. Quest Diagnostics, Inc.*, 2021 WL 6050313, at *6 (W.D. Tex. Aug. 20, 2021). Familiarity with the case is irrelevant as DexCom’s claims do not relate to settled issues. Even if that were not so, transfer could only guarantee familiarity if the case came before the same judge – which it cannot, since Judge Sleet has retired since presiding over the Delaware Litigation.

Delaware is not a convenient forum. This Court should not transfer this case there.

CONCLUSION

DexCom respectfully requests that the Court deny Defendants' Motion to Transfer.

DATED: February 9, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing document was served to all counsel of record, this 9th day of February, 2022, via electronic mail.

/s/ Charles Ainsworth
Charles Ainsworth

EXHIBIT 13

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
WACO DIVISION**

<hr/>)	
DEXCOM, INC.,)	
)	
Plaintiff,)	
)	Civil Action No. 6:21-cv-00690-ADA
v.)	
)	<div style="background-color: black; width: 150px; height: 1.2em;"></div>
ABBOTT DIABETES CARE INC.,)	
ABBOTT DIABETES CARE SALES CORP.)	
)	
Defendants.)	
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**SEALED REPLY IN SUPPORT OF
DEFENDANTS' OPPOSED MOTION TO TRANSFER**

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DexCom’s brief confirms what Defendants said at the outset—the Forum Selection Clause (“FSC”) in the Settlement and License Agreement (“SLA”) requires transfer of this case to Delaware. DexCom does not dispute that transfer to Delaware should occur if a “non-frivolous” license defense exists for any asserted patent claim, that this standard is a “low bar,” and that no private or public factor trumps the FSC. DexCom raises only a single argument opposing transfer there—that Defendants’ interpretation of [REDACTED] in DexCom’s license grant is “frivolous.” But if anyone is advancing weak arguments, it is DexCom, who misstates Defendants’ interpretation, ignores the SLA’s express language, and fails to show that any difference between any possible interpretations matters. DexCom’s opposition at best shows that the interpretation of the license is disputed—and only barely so—not that Defendants’ defense is “frivolous.”

DexCom also fails to overcome Defendants’ showing that N.D. Cal. would clearly be more convenient than this District for this dispute, and that the public interest would support transfer.

I. THE SLA’S FSC REQUIRES TRANSFER TO DELAWARE

DexCom begins with a strawman, asserting without a cite that “Abbott” “argu[es] that DexCom’s pre-2005 patent applications are *prior art* that render certain claims of the Patents-in-Suit obvious.” Opp. at 1.¹ DexCom then asserts that this argument (which is DexCom’s, not Defendants’) “cannot be right” because “claims that are obvious in light of prior art” are not patentable and thus not licensable, and the applications Defendants used are “not eligible prior art.” *Id.* But Defendants did not argue DexCom’s Pre-2005 Applications are “prior art.”

DexCom assumes that if [REDACTED] in the SLA has the same meaning as “obvious” in §103, then the DexCom Pre-2005 Patents and Applications would need to be “prior art” to the asserted claims. This assumption is unexplained, untrue, disputed, and for the Delaware court to decide.

¹ All emphasis is added unless otherwise noted. “Opp.” refers to Dkt. 70. “Mot.” refers to Dkt. 35.

The SLA just [REDACTED]. Notably, §103 itself shows “prior art” is not required by the [REDACTED]. If it were, the statute would not need to say “prior art” separately. DexCom’s other arguments also defeat this assumption. DexCom argues that “a license to claims that are obvious in light of prior art is both incoherent and contrary to public policy.” Opp. at 1, 9. Yet reading [REDACTED] to only reach DexCom’s Pre-2005 Patents and Applications if those patents and applications are “prior art” would limit that part of the license to *only* invalid claims—a result DexCom says “cannot be right” and would be “the epitome of frivolity.” Opp. at 1-2. Defendants agree that DexCom did not hoodwink them into licensing only invalid patent claims. DexCom is the only party evoking an interpretation to achieve that, one that adds “prior art” words that are not there.

DexCom never addresses Defendants’ actual license defense, which faithfully applies the SLA’s language. As the SLA says, [REDACTED]
[REDACTED] *i.e.*, DexCom’s Pre-2005 Patents and Applications. SLA (Dkt. 35-8) at 6 (¶A.13). The SLA specifies what a licensed claim must be an [REDACTED] and that is *not* limited to “prior art.” *Id.* at 5-6 (¶A.13).

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] Mot. at 3.

Even if the SLA or §103 were somehow read to limit the license to claims that are invalid [REDACTED] of “prior art,” Defendants’ license defense would remain meritorious. The Pre-2005 Applications Defendants cite are prior art to the asserted claims, as DexCom tacitly admits in its brief. DexCom does not and cannot dispute that the ’764 Prov. application Defendants cite

against the asserted '215 patent was prior art. According to DexCom, the '764 Prov. became accessible to the public when US2006/0019327 was “published January 26, 2006,” years before DexCom’s asserted “October 30, 2012” “invention” date for that '215 patent. Opp. at 11-12. That is enough for transfer. DexCom disputes whether the '764 Prov. is prior art to the asserted '642 and '213 patents, and whether DexCom’s '168 Pub. is prior art to the asserted '193 patent, but gives the Court no basis to agree with it on those points. The '764 Prov. and the '168 Prov. (“published June 23, 2005,” Opp. at 5) were published years before the '642, '213 and '193 patents were filed in 2020. DexCom has the burden to establish “invention dates” that pre-date the '764 Prov. and '168 Prov., and has not even attempted to do that. *See Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1379-80 (Fed. Cir. 2015). DexCom’s bare allegation that it has an earlier priority date fails to render Defendants’ defense “frivolous.” Opp. at 1, 11.

DexCom’s remaining arguments also fail. DexCom supposes that another “reading of the [REDACTED] refers to the doctrine of obviousness-type double patenting” (OTDP). *Id.* at 8. But DexCom never says OTDP is its reading, the correct reading, or even the better reading of the [REDACTED] language. And DexCom concedes that, in its view, §103 obviousness is one of “only two U.S. standard[s] remotely suggested by the [REDACTED] language.” *Id.* Merely pointing to “one” possibility does not show that the “only other” possibility is “frivolous.” *Id.* That’s doubly true here, where the distinction is without a difference. [REDACTED] [REDACTED] has the same meaning for all material purposes in both the §103 and OTDP contexts. MPEP §804 (cited by DexCom) (collecting cases) (“A nonstatutory double patenting rejection ... is analogous to a failure to meet the nonobviousness requirement of 35 U.S.C. 103 except that the patent disclosure principally underlying the double patenting rejection is not considered prior

art.”); *In re Longi*, 759 F.2d 887, 892, n. 4 (Fed. Cir. 1985) (same).² Tellingly, DexCom identifies no difference it would make if [REDACTED] took its meaning from OTDP instead of §103.

DexCom argues for a “temporal requirement,” that [REDACTED] be assessed as of “the time the invention was made.” Opp. at 11. This at best raises two disputes for the Delaware court to resolve—when the relevant inventions were actually made, and when [REDACTED] should be assessed. It is not a reason the license defense is “frivolous.” The SLA has a 2014 “Effective Date” and [REDACTED] SLA (Dkt. 35-8) at 5-6 (¶A.13), 21 (¶H.3). DexCom makes no argument why temporal language in the statute, which the parties opted not to include in the SLA, would override the parties’ express word choice in the SLA.

DexCom asserts “Abbott may claim a license to all of DexCom’s past, present, and future patents without limitation.” Opp. at 2. This is another strawman. Defendants claim a license only to the patents that DexCom agreed to license, *e.g.*, [REDACTED] of Pre-2005 Patents and Applications. DexCom’s assertion is wrong unless everything DexCom patented and will patent is an [REDACTED] of its Pre-2005 Patents and Applications.³

Finally, DexCom’s argument that Defendants did not assert their license defense “promptly” deserves no weight. Opp. at 4. “Promptly” is not the relevant standard. And Defendants *were* prompt, raising the defense in their first pleading in this case. DexCom never explains when

² The SLA’s use of [REDACTED] is also consistent with §103. *See e.g.*, *CLS Bank Int’l v. Alice Corp. Pty. Ltd.*, 685 F.3d 1341, 1348 (Fed. Cir. 2012), *vacated on other grounds*, 484 F. App’x 559 (Fed. Cir. 2012) (“§§ 102 and 103 broadly ensure that the public remains free to use that which is **known** and **obvious variants** thereof.”).

³ DexCom’s footnote criticizing one of Defendants’ alternative arguments for one asserted claim (because it cites the ’957 patent) is moot. Opp. at 12, n.9. Even if DexCom’s criticism had merit, Defendants showed in Mot. Ex. I at 8-12 that the claim is obvious without considering that patent, and DexCom did not dispute anything that might require reliance on the ’957 patent.

or why Defendants should have suspected any earlier that DexCom would assert licensed claims against them, particularly when DexCom did not engage in the ADR provisions contemplated by the SLA before filing suit.

DexCom’s “frivolousness” argument depends on a mischaracterization of Defendants’ positions and assumptions contradicted by the SLA and basic patent law. DexCom fails to demonstrate any error, let alone frivolity, in Defendants’ SLA interpretation. At most, DexCom suggests the term [REDACTED] is subject to interpretation—a matter that, by agreement, a Delaware court must resolve. Defendants respectfully submit that *General Protecht* and its progeny require transfer so that the SLA may be interpreted and applied in the parties’ agreed forum.

II. IF THE FSC DOES NOT APPLY, N.D. CAL. IS CLEARLY MORE CONVENIENT

DexCom touts that there are some individuals [REDACTED]. But the private factors consider “witness” convenience, compulsory process for “witnesses,” and “sources of proof.” DexCom identifies no likely witnesses, and no claim or relevant issue as to which any [REDACTED] worker or resident in this District is even potentially relevant. DexCom’s patents are not assembly or manufacturing process patents. And DexCom did not even bother to chart [REDACTED] in its infringement contentions. Ex. BQ (Pl. Amended Infringement Contentions, Exs. A-E). DexCom also never addresses N.D. Cal.’s relative convenience. *In re Radmax*, 720 F.3d 285, 288 (5th Cir. 2013) (“[T]he question is *relative* ease of access, not *absolute* ease of access.”) (emphases in original). Compared to the zero potential witnesses DexCom identified in this District, Defendants identified [REDACTED], [REDACTED], Mot. at 13, and DexCom itself identified ten third-party witnesses in California who “may provide testimony regarding” the asserted patents or who were knowledgeable regarding the negotiation and execution of the SLA. Ex. BR, (DexCom Supp. Responses to First Set of Venue-Related Interrogs.) at 9-13. Moreover, all [REDACTED]

[REDACTED] Mot. at 13. [REDACTED]

[REDACTED]

[REDACTED] See, e.g., Ex. BS at 12:5-16, 13:17-25, 44:22-45:6, 56:18-57:3, 68:20-69:1; Ex. BT at 61:7-16. DexCom ignores Federal Circuit precedent emphasizing the importance of the location of accused products' research and development—*not* mere assembly sites. *In re Google LLC*, No. 2021-171, 2021 WL 4592280, at *5 (Fed. Cir. Oct. 6, 2021); *In re Samsung Elecs. Co.*, 2 F.4th 1371, 1380 (Fed. Cir. 2021); *In re Juniper Networks, Inc.*, 14 F.4th 1313, 1319-20 (Fed. Cir. 2021).

III. THE PUBLIC INTEREST FACTORS SUPPORT TRANSFER

The public interest factors support transfer. As to local interest, all parties are incorporated, and thus reside, in Delaware; so Delaware has a strong local interest. *Texas v. Google LLC*, No. 4:20-CV-957-SDJ, 2021 WL 2043184, at *7, 9 (E.D. Tex. May 20, 2021). N.D. Cal., where Defendants are headquartered and [REDACTED] also has a strong local interest. Opp. at 14-15. By contrast, [REDACTED] that DexCom did not even chart does not create a countervailing local interest, as DexCom's own cited authority establishes. Opp. at 14. The Federal Circuit found the exact same Austin Flextronics facility did not support a local interest in this District. *In re Apple*, 979 F.3d 1332, 1344 (Fed. Cir. 2020). Rather, the development of specific accused features—in N.D. Cal., not this District—gave rise to a local interest. *Id.* at 1345. With respect to familiarity with the law, DexCom misses the point. Opp. at 15. This factor relates to familiarity with governing law (not facts), and DexCom cannot dispute a Delaware court is most familiar with the Delaware law governing the SLA.

Defendants respectfully request that their motion be granted.

Dated: February 23, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that all counsel of record are being served with a copy of the foregoing document via electronic mail on February 23, 2022.

/s/ J. Stephen Ravel

J. Stephen Ravel